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Management

Will Emcure's Eribilin be a ray of hope?

PRICE CAP ON ONCO DRUGS WILL IT HAVE THE DESIRED IMPACT?

NPPA's recent move to cap the price of 42 non-scheduled cancer drugs has evoked mixed reactions from the industry. While some berated it as a hasty decision, others have lauded it and believe that it will be beneficial in the long run

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India on USTR's Priority Watch List again

India is once again on the United States Trade Representative's (USTR) Special 301 Report's Priority Watch List. India makes this list for 'long-standing IP challenges facing US businesses in India include those which make it difficult for innovators to receive and maintain patents in India, particularly for pharmaceuticals.'

India has many co-defaulters on the USTR list. Released on April 25, the 91 page report lists 10 other countries, on the Priority Watch List (Algeria, Argentina, Chile, China, Indonesia, Kuwait, Russia, Saudi Arabia, Ukraine and Venezuela.) India's neighbour Pakistan is on the Watch List, along with Barbados, Bolivia, Brazil, Canada, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, Greece, Guatemala, Jamaica, Lebanon, Mexico, Paraguay, Peru, Romania, Switzerland, Thailand, Turkey, Turkmenistan, the United Arab Emirates, Uzbekistan and Vietnam.

Like India, China, Indonesia and Saudi Arabia have been called out specifically for what the USTR considers pharma-related IP violations. China has 'impediments to pharmaceutical innovation' while Indonesia's patent law 'continues to raise serious concerns, including with respect to patentability criteria, local manufacturing and use requirements, and compulsory licensing'. For Saudi Arabia, the Report alleges that 'concerns remain regarding the lack of IP protection for innovative pharmaceutical products, including the lack of adequate and effective protection against unfair commercial use, as well as unauthorised disclosure, of undisclosed test or other data generated to obtain marketing approval.'

Interestingly, for the second year running, India improved its ranking on the 2019 edition of the US Chamber of Commerce's Global Innovation Policy Center's (GIPC) International IP Index by eight places from 44th to 36th. India is nearing the mid mark of this index of 50 world economies representing 90 per cent of global GDP, so we do have quite a way to go.

The question is, will we be safeguarding our national health priorities and standards if we toe the USTR's line or get a better rank on the GIPC IP index? The USTR's remit is 'to use all possible sources of leverage to encourage other countries to open their markets to US exports of goods and services' and 'ensuring that US owners of IP have a full and fair opportunity to use and profit from their IP around the globe'. Inspite of some MNCs introducing tiered pricing arrangements on some products, they are still out of reach of a sizable portion of patients in India.

While the USTR would like patients across the world to pay more for innovation, the irony is that US senators, cutting across party lines, have recently come down heavily on increasing prices of medications. When insulin manufacturers linked rising price to improvements in their products, resulting in better treatment and longer lives for diabetics, Republican Representative David B McKinley rebuked them saying that "innovation is supposed to drive the prices down, not up."

Will we be safeguarding our national health priorities and standards if we toe the USTR's line or get a better rank on the GIPC IP index?

Making the same point, global humanitarian aid organisation MSF says that the USTR report undermines efforts to lower medicine prices globally, pointing out how developing countries like India and Malaysia once again face unfair pressure from the US government over the measures these countries have taken to try to protect access to medicines. *(See full comment: https://bit.ly/2ZAfij5)*

Referring to India as one of the world's most challenging major economies with respect to protection and enforcement of IP, the report mentions previous issues like Section 3(d) of the India Patents Act, as well as new concerns like the January 2019 notice from the Ministry of Health and Family Welfare that allegedly placed further restrictions on the transparency of information about manufacturing licenses issued by states. The USTR sees this as 'a step backward' toward providing an effective system for notifying interested parties of marketing approvals for follow-on pharmaceuticals (generics) in a manner that would allow for the early resolution of potential patent disputes. The report concedes that a small number of India's state authorities, including in Maharashtra and Telangana, continue to operate dedicated crime enforcement units to coordinate IP enforcement activities, but points out that other sates have not followed suit or face organisational challenges.

The USTR report, like the Generalised System of Preferences (GSP) programme, is part of a strategy to use IP rights and trade policies to further a political agenda. According to media reports, a multi-ministerial delegation will be in Washington to convince the US to extend the benefits it provides to India under the GSP programme. The Trump administration has always linked the continuation of GSP benefits to enhanced market access for its dairy products, pharma and medical devices. More recently, beneficiaries of the GSP programme have been warned not to purchase oil from Iran or face the consequences. Balancing trade-related pressures with the realities of escalating healthcare costs and national interests will only get tougher for the next government.

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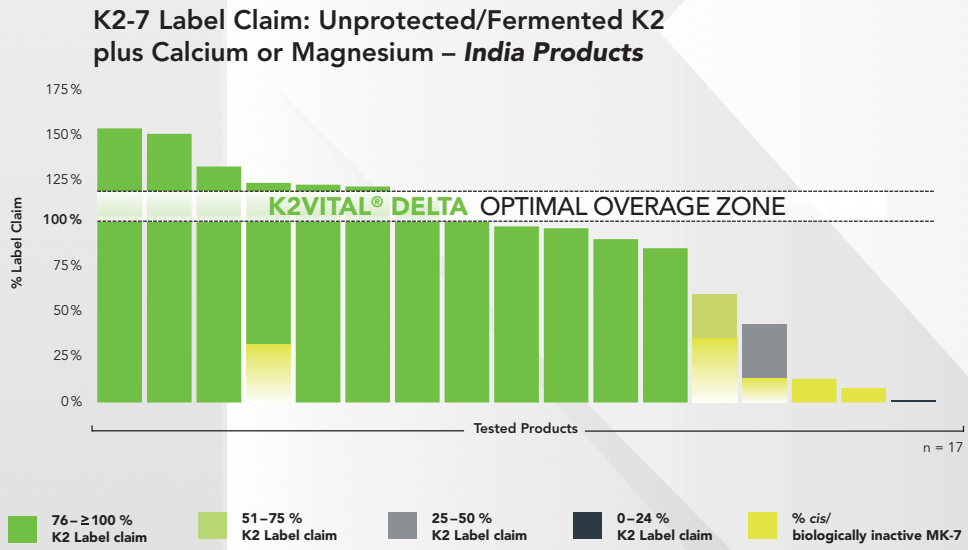

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INTERVIEW

About one-third of the revenues generated by drug companies is spent on transportation

Snowman Logistics, an integrated temperature-controlled logistics services provided has been increasing its pan-India presence with strategically located temperature controlled warehouses, including key markets of Mumbai, Chennai, Bengaluru and Kolkata. **Manoj Pant**, Regional Business Manager - West, Snowman Logistics, speaks on the technological transformations in pharma logistics and how his company is poised to serve the pharma sector, in an exclusive interaction with **Lakshmipriya Nair**

What are the significant changes and improvements that technology has ushered into the logistics industry to meet the demands of an evolving pharma industry?

The biopharma segment is heavily dependent on the cold chain industry, with exports expected to grow by 18 – 20 per cent in terms of value, between 2017 and 2022 *(Source- CRISIL report)*. The cold storage capacity while having grown 1.2 times between 2012 to 2017, has faced several challenges in this time too.

Although the cold chain in terms of pharma is maturing fast, there remain several challenges on the development of a very strict cold chain protocol. Broad challenges are evident in the supply and distribution chains of pharma products.

While most cold chain players operate in multiple segments to ensure better margins and diversification, a few target only the pharma and biopharma segments where margins are higher as quality has to be maintained.

The industry is still undergoing constant technological advancements to ensure smooth operations where the quality of pharma products is unhindered.

Some of the technological advancements include:

Drone scan with RFID technology for inventory and barcode scanning: Usually, logistical items are tracked and traced through the reading of essential codes. Commercially, different type of readers are available for reading such codes such as barcode reader, QR Code reader, RFID reader, etc.

With the introduction of DroneScan technology, large warehouses can now opt for a robotic solution to take stock (inventory), providing live feedback and integration with Warehouse Management systems. DroneScan uses a drone to scan the barcode on each pallet and records the location of each item in the warehouse management system, proving to be up to 50 times faster than manual capturing. At present, this technology is being used by large e-commerce companies and we may soon find many pharma organisations using this technology in warehouse inventory management.

Cloud technology for data storage: Cloud-integrated logistics not only provides data

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in real-time but also makes it accessible to the entire team, regardless of location or time. Universal accessibility makes processes that require round-the-clock monitoring far easier to handle. This provides real-time visibility into logistic processes and data, which helps to keep operations under control.

Cloud-based master data for tracking: With the use of master data, cold chain companies can get real-time insights into the availability of materials and products to reduce supply chain risks and optimise costs.

Temperature tracking using IOT cloud: To avoid breakdowns, cold storages can deploy IoT-enabled monitoring solutions like embedded sensors. When installed throughout a cold chain facility, these sensors collect data on environmental conditions and promptly send alerts. They transmit the gathered data to warehouse management systems fostering a coherent tracking network.

When IoT-based solutions come into play, there is no need to check environmental conditions of cold storage manually. Apart from real-time asset tracking, the data obtained through the IoT-powered sensors provide a better understanding of risks involved, helps improve operational output and distribution schedules. This inevitably translates into high customer retention, as cold chain logistics become more streamlined and visible.

How is the cold chain pharma logistics landscape in India changing? What are the driving factors?
The latest in the pharma landscape is the aggressive growth of biologics and biosimilars, both of which need temperature-controlled storage. Fortunately for India, we hold the title of having the largest cold storage capacity in the world. Although previously labelled by experts as insufficient and the leading cause for high annual wastage levels, India's cold storage facilities have now been improved.

India's cold chain management in general, however, needs some organising with lacking infrastructure and disjointed supply chains hindering the market's growth. Stakeholders need to obtain and increase their accountability to improve the quality and streamlining of operations in pharma.

India's cold chain management needs organising with lacking infrastructure and disjointed supply chains hindering the market's growth. Stakeholders need to obtain and increase their accountability to improve the quality and streamlining of operations in pharma

What are the technology trends that are revolutionising the processes and operations of a cold chain? Can you elaborate on their potential?
The cold supply chain segment would showcase supply chain technologies. The key solutions represented include 3PL/4PL companies, logistics service providers (LSPs) specialised in the movement of temperature-sensitive goods, tracking & tracing and cold supply chain experts. A third-party logistics provider provides outsourced logistics services to companies. These services can make up part or sometimes all of their supply chain management functions, including:

- Inventory storage and management
- Picking and packing
- Freight forwarding
- Shipping/distribution
- Customs Brokerage
- Contract management
- IT solutions
- Cross-docking

A fourth-party logistics provider essentially takes third-party logistics a step further by managing resources, technology, infrastructure, and even manage external 3PLs to design, build and provide supply chain solutions for businesses.

4PL services typically encompass 3PL services as well as:

- Logistics strategy
- Analytics including transportation spend, analysis, capacity utilisation, and carrier performance

Freight sourcing strategies

- Network analysis and design
- Consultancy
- Business planning
- Change management
- Project management
- Control tower and network management services, coordinating a wide supplier base across many modes and geographies
- Inventory planning and management
- Inbound, outbound and reverse logistics management

What is the kind of training and education required for personnel of cold chain logistics to take advantage of the growth potential in the pharma sector?
As per recent CRISIL research reports, the Indian cold chain industry is expected to log a compound annual growth rate of 13-15 per cent in the five fiscal years, through 2022, as compared to 11-13 per cent in the previous five fiscal years. This will swell the industry to Rs 47,200 crores in the fiscal year 2022, from Rs 24,800 crores in the fiscal year 2017.

To achieve this result, reskilling and upskilling are the key requirements. The identification of the right skill sets, and the fulfillment of skill gaps are perennial issues that the industry faces and a lack of formal curriculum at institutions add to the woes of growth. Onboard and off-board diagnostics, analysis of dash boards and understanding the technology are all vital for cold chain logistical organisations, so there should be skilled from the bottom of the pyramid right up to the top.

What are the complexities in the current pharma supply chain that can be tackled with the help of Snowman Logistics' solutions and services?
Pharma cold chain management is an important aspect of the supply chain in the healthcare industry. The cold chain logistics services help the pharma and healthcare industries maintain a continual stock of drugs from suppliers and distributors across varied locations.

For pharma shipments with temperature-controlled products that are handled multiple times from supplier to end user, quality assurance requires a combination of temperature control, monitoring tools and coordinated actions throughout the supply chain. They face several challenges to achieve this, of which the biggest challenge within the cold chain is to maintain the 2°C - 8°C range throughout the delivery cycle, which is the most common range for the phrma industry. As the pharma cold chain industry expands its reach, manufacturers, logistics providers and carriers will need to continue to coordinate actions to address the ongoing challenges of cold chain logistics.

The current pharma supply chain scenario in India is extremely complex. The presence of more than 55,000 retail pharmacies which are spread across India is one of the main reasons for this complex supply chain environment. Poor infrastructure and transport facility is a big obstacle for cold chain supply. About one-third of the revenues generated by drug companies is spent on transportation.

The problem of poor supply chain management becomes even more severe when temperature-sensitive drugs, such as polio vaccines, are required to be transported to remote areas. Hence, the presence of a proper supply chain management, which includes temperature-controlled vehicles and warehouses, have become important for the pharma industry of India. Vaccines require the support of temperature-controlled environments right from the point of their initial stage of production, up to their final distribution.

Every cold storage of ours adopts the latest available technology without any compromise. Our facilities are well designed to take care of any type of products. We can maintain temperatures ranging from +25°C to -25°C, which is the widest range available in India. The facilities are well designed and operated to meet the best quality standards globally, i.e., BRC and ISO 22000.

In addition to building the best in infrastructure, implementing the best processes for efficiency, quality and service are must in this business. A cold storage operator must provide services throughout, from domestic players in an unorganised sector to the top global brands. Snowman Logistics has included certain Information Technology (IT) tools to come up with the best service levels. We have also introduced technology by which we can monitor temperature at the chamber level through our mobile phones. A 24x7 Command Centre has been made functional to monitor and troubleshoot our vehicle and cold storages. An app-based touring and auditing system allows our customers to get almost live visibility of the trucks unloaded and loaded at our facility, right to the SKU level information.

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PRE EVENTS

Learn GMP Workshop to be held in Mumbai

All set to take place on June 15 this year, participants at this seminar will talk about a holistic towards remediation of non-compliances and 483s

QUALITY SOLUTIONS is organising the third edition of GMP Workshop that will take place in Mumbai on June 15, 2019 and will focus on how to handle 483s and FDA warning letter, while also understanding the differences in approaches of US FDA, EU and other regulators.

There will be discussions on most frequent categories of 2017 and 2018 across the world, laboratory-related 483s and importance of computer validation, understanding inspection and preparing for it as expected by FDA. It will also focus on how to define tasks and assigning personnel to specific tasks for the inspection, facility requirements to support the inspection (front room, back room), the value of mock audits, how personnel should conduct themselves during the inspection and the inspection process and the process of dealing with all other audit non-compliances, and mindset of investigation at department head level.

> Discussions will be held on most frequent categories of 2017 and 2018 across the world, laboratory-related 483s etc

The topics of learning at the workshop are as follows:

- Review of 2017 and 2018 483s
- Laboratory-related 483s and NCs
- Computer/software system validation
- Data storage, archival and data integrity
- Challenges in software execution and its long-term benefits
- Importance of inspection management skills
- Building quality culture for all-time readiness
- Importance of human aspect in inspection and during remediation
- Remediation approach for 483s Vs EU and other countries

The beneficiaries include those who are supposed to face audit and are involved in preparing replies, quality/regulatory management, corporate QA management, manufacturing management, QC management and IT/engineering management.

EP News Bureau

Formulation R&D leaders to congregate at FDD Conclave 2019 in Hyderabad

In its third edition, the conclave this year will focus on the theme: Preparing for the next frontiers in FDD

ORGANISED BY *Express Pharma*, FDD Conclave 2019 will be held from June 7-8, 2019 at Novotel Airport, Hyderabad. It is a thought leadership platform for formulation scientists and R&D heads of pharma companies to come together and converse on the current and future trends in the industry, their growth drivers and challenges, as well as strategies to fast-track progress in the sector.

Now in its third edition, this year's FDD Conclave will focus on the theme: Preparing for the next frontiers in FDD. It will focus on the huge potential of drug development and delivery systems to create intellectual property, improve life-cycle management, gain cost and market differentiation and thus become major determinants of success.

FR&D leaders of India Pharma Inc will congregate at FDD Conclave 2019 to share their learnings as they explore and experiment with different dosage forms, compositions and drug delivery options, be it through oral, pulmonary, nasal, transmucosal or transdermal routes, in their continuous quest for improved methods of development, manufacture, and administration of medicines.

The two-day event will also highlight how pharma companies will have to continue making significant investments on new-age technologies and complete their digital transformation to ramp up their R&D productivity and achieve next generation of scientific breakthroughs.

Besides, industry captains will discuss strategies which will help augment their product pipelines with formulations which are faster and more efficient such as fast-dissolving drug formulations, multiparticulate dosage forms and complex drug delivery systems while retaining their cost-competitiveness.

Thus, for the 100+ leading pharma professionals attending the event, the two-day event will give an opportunity to:

- Get updated on the advancements in India's pharma formulations and drug delivery sector
- Demonstrate your pharma formulation capabilities and showcase your innovative solutions
- Gain insights from thought leaders of the pharma and biotech industries
- Acquire access to solution providers with cutting-edge technologies
- Discuss on the role of formulation and drug delivery in gaining a competitive edge
- Network with who's who of the pharma industry

EP News Bureau

6th edition of PharmaLytica to be held in Mumbai from June 10-12, 2019

The 6th edition will see a new pavilion for API and excipients

THE 6TH edition of PharmaLytica will be held in Mumbai from June 10-12, 2019 at the Bombay Exhibition Centre in Goregaon (E). In the 6th edition of this international trade fair and conference, the pharma community can pick up on the latest industry trends, innovations and do business with analytical, laboratory, machinery and packaging industry. In a first, the 6th edition will see a new pavilion for API and excipients.

PharmaLytica conference, collocated with the exhibition is the knowledge forum and important industry gathering that will bring an entire range of topics in analytical, outsourcing, laboratory, scientific and biotechnology sector. PharmaLytica is evolving as the leading marketplace for products and services along the entire value chain in niche segments within the pharma industry.

Express Pharma is the media partner for the event, with CIPI as the Association partner.

The Innovation Gallery will display innovative products from leading exhibitors. Visitors can attend the gallery for free and at one location to see a wide range of new products and technologies in the market. More than 300 exhibitors will congregate at the venue which will be spread around an area of 12000+ sq mts.

EP News Bureau

POST EVENT

7th DIA India Pharmacovigilance Conference held in Mumbai

The two-day conference discussed the latest trends and developments in pharmacovigilance, drug safety and medical affairs and the impact of innovations like artificial intelligence, machine learning, automation and real-world evidence on driving better safety outcomes

DIA INDIA recently organised the 7th Pharmacovigilance Conference in Mumbai on the theme 'Transforming Clinical Safety and Pharmacovigilance.' The two-day conference discussed and explored the latest trends and developments in the space of pharmacovigilance, drug safety and medical affairs and the impact of innovations like artificial intelligence, machine learning, automation and real-world evidence on driving better safety outcomes. The programme, created under the expert guidance of Moin Don, President and CEO, PVCON Consulting as programme chair, Dr Krishna Bahadursingh, Fellow of the Faculty of Pharmaceutical Medicine (UK) as co-chair , and a stellar programme committee of senior industry executives from the Indian healthcare fraternity, was successful in fostering international exchange of actionable regulatory, medical and commercial insights to advance drug safety and pharmacovigilance.

With seven individual sessions, over 15 presentations and two panel discussions, the 7thPharmacovigilance conference convened 31 distinguished national and international subject matter experts from regulatory, industry,and academia. It engaged global decision makers and influencers with more than 200 professionals participating from the pharmaceutical, biotechnology

services and academic global communities .

Day one of the conference witnessed the keynote session by Dr YK Gupta, Former Dean, AIIMS, New Delhi, wherein the Indian clinical trial safety scenario and the changing regulatory landscape for drug safety in India were discussed. This session was followed by presentations focussing on global regulatory developments in pharmacovigilance including ICH E2B (R3), FAERS, Eudravigilance The impact of Brexit was also discussed in a session led by Dr J Vijay Venkatraman, MD and CEO, Oviya Medsafe.

Another session kicked was off with a presentation on 'Reimagining Case' processing with Artificial Intelligence by Soumyanarayan Srinivasan, MD, Accenture Lifesciences and Sumanta Ghosh, Pharmacovigilance Practice Lead, discussing the increasing automation with disruptive technology and its positive impact on quality and patient safety. The following panel session moderated by Moin Don and Anju Agarwal, Head, Pharmacovigilance, Advanz Pharma, led to several interesting questions from the audience on the result of digital transformation and its impact on jobs in the future. The industry stalwarts part of this panel opined on the changing landscape with job role evolution instead of head count reduction and the transition from safety data management to safety data science which will pave the way for next generation pharmacovigilance professionals.

In the course of this discussion, talks were held on the impact of digitisation on audit requirements. In coming times as safety management gets more automated, it is pertinent to stay in line with changing regulatory requirements. Some insightful questions were brought concerning best practices, implementing learning from other industries and the outlook from different regulators.

One of the sessions witnessed industry stalwarts discuss emerging trends in pharmacovigilance and upcoming business models in safety. This session included presentations about the role of various drug safety professionals in changing times and through consolidations, mergers and acquisitions. Dr Ute Heffner, EU QPPV, Glenmark Arzneimittel talked about the management of a global PV system and the alignment required across regions to disseminate safety information globally. The day ended with the last session focussing on the upcoming business models in pharmacovigilance and the emerging hybrid outsourcing trends.

> In coming times as safety management gets more automated, it is pertinent to stay in line with changing regulatory requirements

Day two kicked off with Dr Dhananjay Bakhle, Executive Vice President, Medical Research, Lupin, delivering his address on striking the right balance between safety and survival in cancer immunotherapy. The session touched upon the complexities of safety management in oncology trials and overcoming the challenges.

This was followed by an engaging session on the role of medical affairs- 2020 and beyond, chaired by Dr Aamir Shaikh, Founder, Assansa. The session delved deep into the evolving role of medical affairs today and the competencies to be developed for the next phase. Dr Vinod Mattoo spoke on how the role of medical affairs is combining with pharmacovigilance locally and globally. This was followed by Dr Krishna Bahadursingh discussing the safety issues in immune-oncology and approaches to the same in light of the evolving medical and safety practices.

A session named 'Evolving Systems and Approaches to Effective Pharmacovigilance-Emerging Markets session', had Rawya Al Kredly, Head, Pharmacovigilance, Julphar Pharma UAE and Manoj Swaminathan, Head, Global Pharmacovigilance, Piramal Enterprises, discuss emerging PV practices and guidelines in the middle east and emerging markets including China, Korea and ASEAN region.

A panel discussion chaired by Dr Krishna Bahadursingh, along with senior executives from Indian biopharma and services organisations highlighted the impact of digitisation on audit requirements..

The last session of the event chaired by Dr Retesh Kumar, Global Safety Practice Lead, Cognizant Technology Solutions on enhancing patient safety through enhanced vigilance practices saw Dr Dnyaneshwar Sanap, Associate Director, Risk Management, Boehringer Ingelheim, Germany, discuss the planning, execution and monitoring of effectiveness of risk minimisation activities by sharing some real-life cases. Following Dr Sanap, Dr Dhanaraj E, Global PV Lead, Biocon shed light on the risk and safety aspects of biosimilars and lastly, presentation of the day by Kanchan Sakhare from Cognizant Technology Solutions discussed process re-engineering to enhance quality.

EP News Bureau

EVENT BRIEFS

6TH EDITION OF PHARMALYTICA

Date: June 10-12, 2019
Venue: Bombay Exhibition Centre in Goregaon
Summary: In the 6th edition of this international trade fair and conference, the pharma community can pick up on the latest industry trends, innovations and do business with analytical, laboratory, machinery and packaging industry. For the first time ever, the 6th edition will see a new pavilion for API and excipients. PharmaLytica conference, collocated with the exhibition is the knowledge forum and important industry gathering that will bring an entire range of topics in analytical, outsourcing, laboratory, scientific and biotechnology sector.

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LEARN GMP WORKSHOP

Date: June 15, 2019
Venue: Mumbai
Summary: Quality Solutions will organise the third edition of GMP Workshop which will focus on how to handle 483s and FDA warning letter, while also understanding the differences in approaches of US FDA, EU and other regulators.

There will be discussions on most frequent categories of 2017 and 2018 across the world, laboratory-related 483s and importance of computer validation, understanding inspection and preparing for it as expected by FDA. It will also focus on how to define tasks and assigning personnel to specific tasks for the inspection, facility requirements to support the inspection (front room, back room), the value of mock audits, how personnel should conduct themselves during the inspection and the inspection process and the process of dealing with all other audit non-compliances, and mindset of investigation at department head level.

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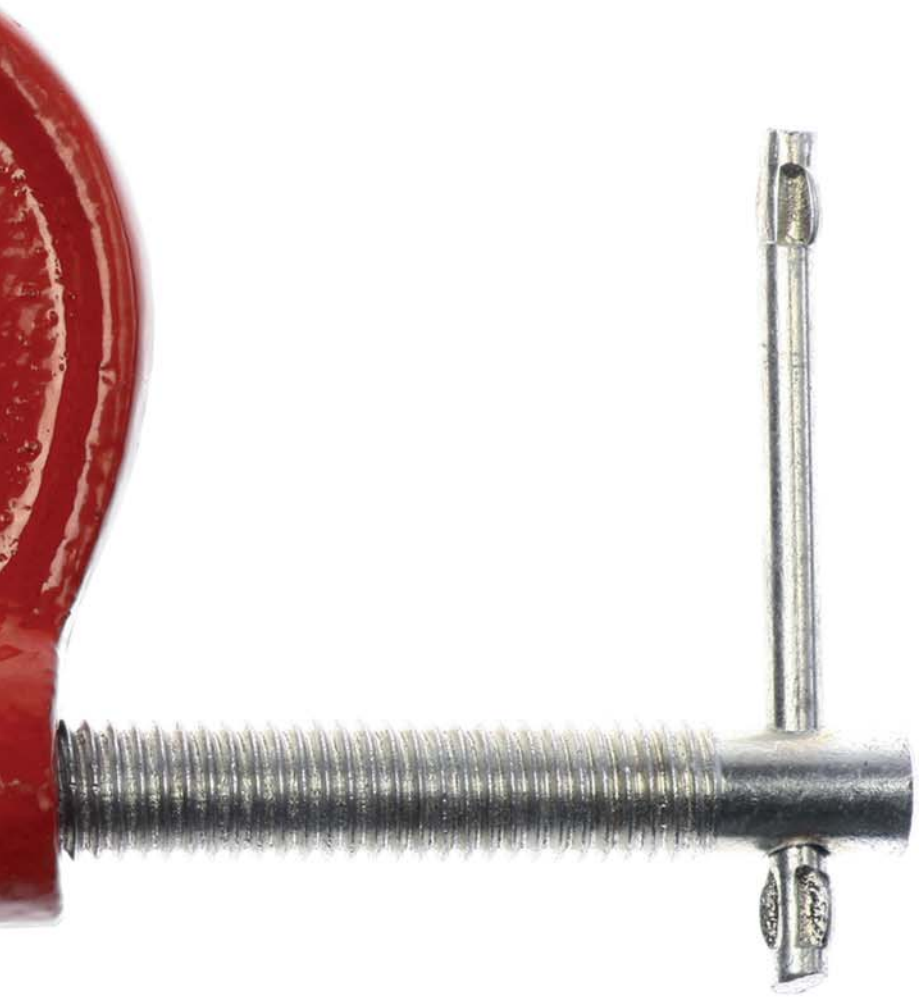
CAP ON ONCO DRUGS WILL IT HAVE THE DESIRED IMPACT?



NPPA's recent move to cap the price of 42 non-scheduled cancer drugs has evoked mixed reactions from the industry. While some berated it as a hasty decision, others have lauded it and believe that it will be beneficial in the long run

By Akanki Sharma

The price cap on 42 non-scheduled cancer drugs by the National Pharmaceutical Pricing Authority (NPPA), which was set to be a relief for cancer patients is just a pyrrhic victory, inform experts, as cancer patients still feel the sting of 'out-of-pocket-expenses.' Some stakeholders — drug manufacturing firms, hospitals and pharmaceutical associations — believe that the move was implemented in haste and it needs a 're'view.

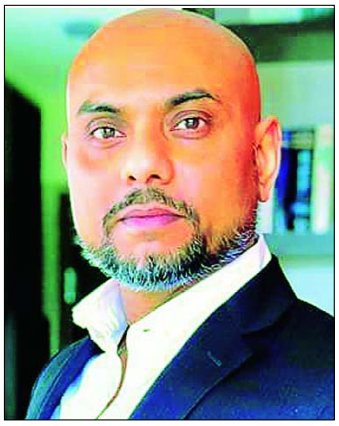
Elaborating on whether the move is beneficial for pharma companies, Kiran Mazumdar Shaw, CMD, Biocon, believes that if such decisions are made in "fits and starts", though with an intention to fix something, the goal remains largely unfulfilled.

"I think we need to look at all our policies in a holistic way. Just reducing drug prices doesn't really solve the problem. We have got to look at all the healthcare costs holistically if we really want to build enduring sustainable models," she adds.

Agreeing with her, Rakesh Pandey, CMD, Bravo Pharmaceuticals, a drug manufacturing and distribution company with sales in India, Central Asia and Eastern European countries, says that this step taken by NPPA is not good in terms of business for the pharma companies which are export-oriented and their target market is India. "This move gains significance in the government's attempt to provide affordable healthcare. The authority has noted that despite the fact that India is the pharmacy of the world, out-of-pocket expenses on medicines is the largest cause for pushing families beyond the poverty threshold. Pharma companies, on the other hand, can now target the volume-based big markets otherwise it's not going to benefit them," he points out.

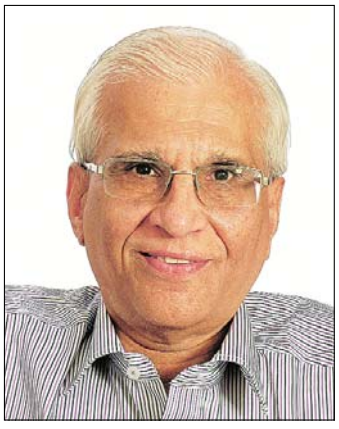
Just reducing drug prices doesn't really solve the problem. We have got to look at all the healthcare costs holistically if we really want to build enduring sustainable models

Kiran Mazumdar Shaw
CMD, Biocon



Though the retail prices are not likely to be significantly affected through this move, the patients will benefit from the treatment centres through margin gaps

Rakesh Pandey
CMD, Bravo Pharmaceuticals



This move not only makes the system more transparent, but also helps the patients deal with huge medical bills due to expensive drugs used in oncology sector. Hospitals will also gain from the fact that more and more patients would be able to afford healthcare now

Dr Suresh Advani
HOD-Medical Oncology,
SL Raheja Hospital, Mahim-a Fortis Associate Hospital

Export, import and discounts

According to the latest India Equity Brand Foundation report, the Indian pharma market is the third-largest in terms of volume and 13th largest in terms of value. While pharma exports from India stood at $17.27 billion in 2017-18, the industry is expected to grow at a compound annual growth rate (CAGR) of 22.4 per cent to touch $55 billion by 2020. Of late, Union Minister for Commerce and Industry, Suresh Prabhu had also informed the country that for the 'first time,' India has crossed $19 billion mark in pharma exports this fiscal.

In line with this, Pandey says, "Our company is export-oriented and our target market is Africa and Central Asia, and the price reduction gives us advantage in the market because we first export medicines from India in bulk to our units in Europe and Africa and Central Asia and after that it's further processed to be sold in those markets. For the consumer in Indian markets, the price is going to play a big role and it will be one of the most important factors to improve the availability for the mass consumers."

Apart from it, he mentions discounts as a common part of sales strategies because of the prohibitive prices of the cancer drugs. "Though retail prices are not likely to be significantly affected with this move, through margin caps, patients will benefit from treatment centres. In this way, the price cut is expected to benefit around 22 lakh cancer patients in India and would result in annual savings of around Rs 800 crore for the patients," he adds.

In the long run

Any decision taken by an authority brings its pros and cons with it. So is the case with this resolution, as some feel that the step was taken in a haste, while others suggest that it is going to be beneficial for the pharma sector in the long run.

In accordance with this, a spokesperson from Intas Pharma is of the view that the step by NPPA on fixing the trade margin will definitely bring down the MRP of anti-cancer drugs benefitting thousands of cancer patients in the country. "In the short term, this move may not be beneficial, but in the long term, it would be beneficial for the industry because of the increased penetration and treatment rate," the spokesperson claims.

Asked about the impact of this decision on the company, the person informs, "There has been no impact on the business except on the operational aspect as we had to ensure that existing lot of medicines are stickered with revised MRP, and submission of revised MRPs to all cancer hospitals. We were amongst the first pharma companies to ensure availability of revised MRP medicines thereby preventing any drug shortage. The move by the government is an important step in reducing the treatment cost for cancer patients and thereby

making it accessible to a large section of the society. As a part of the pharma industry, our endeavour is to make the treatment accessible to all and we will be happy if this move is able to create a balance between drug manufacturers and consumers."

Dr Suresh Advani, HOD-Medical Oncology, SL Raheja Hospital, Mahim — a Fortis Associate Hospital, also believes that NPPA's decision will prove beneficial for patients, doctors, and even hospitals in the long run. "It not only makes the system more transparent, but also helps the patients deal with huge medical bills due to expensive drugs used in oncology sector. Hospitals will also gain from the fact that more and more patients would be able to afford healthcare now," he asserts.

According to Advani, this is a positive step which will make more and more patients trust corporate hospitals. "The maximum gain is for consumers and drug manufacturers. This move brings more transparency in the system and benefits both the producer and the consumer," he highlights.

Mentioning an another important aspect related to the NPPA's decision, Advani says, "My patients can now afford treatment at tertiary care hospitals like Fortis. The ambiguity of pricing is now resolved, with fixing of the Maximum Retail Price (MRP)."

Anil Dutt, Partner, Lakshmikumaran & Sridharan Attorneys, opines, "Whether or not the cut in anti-cancer drug prices would be beneficial for pharma companies, is something that can be contemplated in due course." Elaborating further, he says, "NPPA has capped the trade margins for these drugs, placing a restriction on the drug price at first point of sale product, i.e. the price at which the manufacturer sells the drug to the stockist. While for some brands, the revised prices may lead to losses considering the input cost, there would be others wherein the profit margins would be reduced and some may even remain unaffected. For instance, when it comes to single-unit drugs, which are the most expensive, the prices remain unaffected, so profits can still be made by the pharma companies manufacturing such drugs. It will, therefore, depend on a drug-to-drug basis."

The case of accessibility and affordability

By capping trade margin at 30 per cent, the government has brought 72 formulations and 355 brands (as per NPPA data) under price control, reducing their retail prices by up to 85 per cent, in turn, making the treatment affordable and accessible for cancer patients.

Dutt says that accessible and affordable cancer treatment is the most significant impact that this move can have or rather, is intended to have. He tells, "As not much time has passed since the revised prices were notified by the NPPA, it is too soon to judge the impact at the ground level. Nevertheless, one positive impact that can be foreseen is that because of the price regulation, the hospitals would find it difficult to charge the exorbitant prices that they were charging for these treatments. But then again, that might lead to reduction in hospital's revenue which may affect the treatment quality."

Disagreeing with this

view, however, Daara Patel, Secretary General, Indian Drugs Manufacturers' Association, says, "The NPPA move reducing anti-cancer drug prices is certainly beneficial to patients with the prices being reduced by more than half for many drugs."

He adds, "Similar to medical devices, anti-cancer drugs are invariably high-priced and are sold directly to hospitals. In most instances, the hospitals decide the MRP with a hefty margin for themselves and the patient has no choice but to pay."

Shedding light on the impact this move would have on pharma firms, he says that it may not negatively impact pharma companies, as the prices have generally been reduced to realistic levels.

While this price reduction witnesses criticism too, Patel points out, "When non-scheduled anti-cancer drugs were being billed at inflated MRPs by hospitals to patients, there was no objection. Now that government has stepped in to drastically reduce prices, they are allegedly worried that the margins are capped at 30 per cent, and the potential of shortage of these drugs. The Indian pharma industry, rest assured, will continue producing these and other drugs, as has been the case all these years, whether controlled or de-controlled, because the interest of the patient is supreme."

Prima facie, it appears that the move has struck a balance between drug producers and consumers. However, we will have to wait and see how the judiciary deals with this issue

Anil Dutt
Partner, Lakshmikumaran & Sridharan Attorneys

The step taken by NPPA may not negatively impact pharma companies, as the prices have generally been reduced to realistic levels. The Indian pharma industry will continue producing these drugs, whether controlled or de-controlled, because the interest of the patient is supreme

Daara Patel
Secretary General,
Indian Drugs Manufacturers' Association

Over the past years, the number of cancer deaths in India in 2018 was nearly eight lakhs, which is alarmingly high. As per NPPA, the number of cancer cases is likely to double by 2040. Even the WHO has reported that cancer is presently the leading cause of deaths in India.

Stating the above-mentioned facts, Dutt also emphasises, "Through this price-reduction, NPPA clearly wants to make cancer treatment more affordable and accessible, and in that context, it can be seen as a step towards public welfare. There is concern across all stakeholders regarding this move, including the consumers. It can only be seen with time how the same is resolved by the authorities. *Prima facie*, it appears that the move has struck a balance between drug producers and consumers. However, we will have to wait and see how the judiciary deals with this issue.

"While the pharma companies may be incurring huge costs in R&D or coming up with new drugs, the same cannot be permitted to go unregulated. Since public welfare is at the core, there has to be a balance between the pharma companies and the consumers," he concludes.

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Will Emcure's Eribilin be a ray of hope?

At approximately 40 per cent of the cost of the innovator, Emcure Pharma's Eribilin is definitely a more cost effective alternate to Eisai Pharma's Halaven but clinicial outcomes will depend on the quality of the generic drug

By **Usha Sharma**

The cancer market in India is a very niche segment as compared to the pharmaceutical market consisting of acute and other chronic therapies. Almost all pharma companies, including domestic and multinational entities, operating in the market are striving to expand their portfolio. According to information available in the public domain, India's onco drug market comprises 140 molecules with 1337 brands. Most MNCs are present in the market with their originator products, whereas domestic pharma companies with generic versions. The latter are generally more affordable than the former and in the case of small molecule drugs. Crucially, both versions have the same chemical composition delivering the same health outcomes.

Growing incidence of cancers

Four top cancer research groups, namely; American Cancer Society (ACS), Cancer Prevention and Control (CDC), National Cancer Institute (NCI) and North American Association of Central Cancer Registries (NAACCR) have recently released their 2018 Annual Report in the US. The report provides an update on the Status of Cancer disease, which highlights overall, cancer death in the US. The report mentions that cancer death rates for women have declined an average of 1.4 per cent per year over the most recently studied five years while incidence rates have remained stable.

As per the information available in the public domain, breast cancer is the most common cancer in women and 271,270 new cases are expected in the United States in 2019. The next most common cancers are lung cancer and prostate cancer. In India, as well, breast cancer remains the most common cancer in women. With an age-adjusted rate of 25.8 cases per 100,000 women and a mortality rate of 12.7 per 100,000 women. Incidence of metastatic breast cancer (MBC) has been reported to be approximately five per cent to 25 per cent from various centers in India.

Various Indian studies suggest that about 20 per cent of breast cancers are triple-negative breast cancers. Triple-negative breast cancer (TNBC) is cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2 protein. It means that the growth of the cancer is not fueled by the hormones estrogen and progesterone, or by the HER2 protein. Even though chemotherapy may work well for this type of breast cancer, the chance of relapse is high and the overall prognosis is poorer than the other types of breast cancer.

Do we have solutions?

To make cancer drugs accessible and affordable the Government of India cracked down on prices of onco drugs in the past one year. The latest anouncement on the capping of trade margins of 42 cancer drugs is one example of this stance.

Cancer therapy could also get more affordable as key onco drugs go off patent in the next few years. For example, Roche's Avastin (bevacizumab) who's patent expires in 2020. Roche's Herceptin (trastuzumab) also goes off patent in 2019 in the US. Another important patent expiry being tracked is that of Eisai Pharmaceutical's Halaven's (eribulin) with the first of five patents in the US expiring on June 16 this year.

One of the first generic versions of eribulin for the treatment of metastatic breast cancer (MBC) was recently

launched by India's Emcure Pharmaceuticals in March.

Commenting on the launch Sainath Iyer, President – Business Strategy & Specialty Business – Emcure Pharmaceuticals said, "Under the guidance of Dr Mukund Gurjar (CSO), the company worked on this molecule for about a year focusing on both API and formulation development. The chemical structure of this API is one of the most complex molecules ever commercialised. A group of highly-trained Ph D level scientists were able to accomplish this challenging task in a very short period of time."

Explaining the quality process and regulatory compliance in Eribilin, he informed that, "Chemically both (Eisai's Halaven and Emcure's Eribilin) molecules are same. Eribilin is not different from Eisai's Halaven. It's the first generic version, which will have a same dosing regimen as of Halaven."

When we contacted the innovator of Halaven, Eisai Pharma, to comment on the quality and impact of drug in the Indian market, Dr Sanjit Singh Lamba, Managing Director, Eisai Pharma said, "We acknowledge the launch of Emcure's Eribulin; however, we cannot comment on its impact at this moment as we don't know their product."

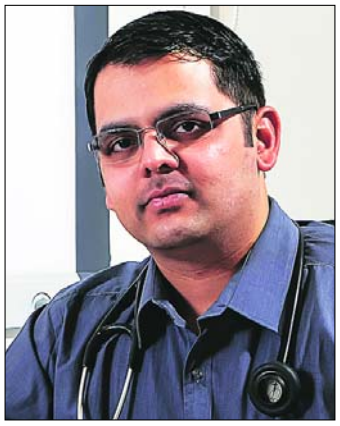
In India, Halaven is the recognised chemotherapy brand in MBC in its fifth year of launch. And it is approved for subtypes steroid sulfatase (STS).

We are offering the drug at a price which is 40 per cent lower than the innovator, thereby increasing the patient pool, who will now be able to afford this drug

Sainath Iyer
President – Business Strategy & Specialty Business – Emcure Pharmaceuticals

We acknowledge the launch of Emcure's Eribulin; however, we cannot comment on its impact at this moment as we don't know their product

Dr Sanjit Singh Lamba
Managing Director, Eisai Pharma



History has shown evidence that the availability of generic drugs at an affordable cost makes the drug available for larger group of patients by providing an option

Dr Adwaita A Gore
Consultant Medical and Paediatric Oncologist, Hemato Oncologist & Bone Marrow Transplant Physician, Prince Aly Khan Hospital and Zen Multi Specialty Hospital

After story...

In India about 20 per cent of breast cancer patients have triple negative breast cancer. In terms of values, this niche segment is approximately Rs 50-60 crore. With this launch, Emcure will have access to a considerable business market. Commenting on the Indian metastatic breast cancer market and business potential, Iyer said, "We at Emcure are targeting to catch 25 per cent of this market. At the same time, we are planning to expand the market by offering the drug at a much cheaper price for the benefit of patients."

The high treatment cost made it difficult for many patients to opt for it. Hence, the innovator of Halaven introduced a tiered pricing programme. Informing more about the programme, Lamba said, "As the originator of Halaven and the first to launch a tiered pricing programme in this area, we aim to further contribute to increasing the quality of life of patients with MBC in India."

Will Emcure be considering the same feature to increase accessibility?

Iyer comments, "We are offering the drug at a price 40 per cent lower than the innovator, thereby increasing the patient pool, who will now be able to afford this drug."

The cost plays an important role and generic players too. During the launch of Eribulin, Iyer informs, "Incidence of breast cancer is on the rise in India and being a price sensitive market with low awareness, we aim to provide a proven and cost-effective treatment of high quality and efficacy as offered by the innovator brand and it is a cost-effective option for patients,"

Adhering to quality

Eribulin is an injectable medicine and needs to be administered by a qualified physician consultant. Dr Adwaita A Gore, Consultant Medical and Paediatric Oncologist, Hemato Oncologist & Bone Marrow Transplant Physician, Prince Aly Khan Hospital and Zen Multi Specialty Hospital says, "Eribilin (Emcure) is the first Indian generic developer after the innovator Halaven (Eisai Pharma). History has shown evidence that the availability of generic drugs at an affordable cost makes the drug available for larger group of patients by providing an option."

The toxicity profile of the drug is as low as compared to other drugs and is well tolerated. Infusion time is 2-5 min which is short and would not require longer hospital stay. Since the drug is administered intravenously, physicians can closely monitor and the actual requirement of the drug can be managed. Stressing on how eribilin will comply patient adherence Iyer informs, "IV drugs can be monitored closely and thereby the compliance is high. The physicians also need not worry about a patient missing a dose or taking an extra dose like in the case of oral drugs.

Commenting on the adherence aspect, Gore said, "It helps in expanding the market and opens a different option for therapy. The drug schedule is very comfortable for patients as it can be administered in a day care setting and does not require long hospital stay. The adherence depends on multiple factors and drug cost and convenient dosing are just two of many parameters in consideration."

While judging the drug quality and confidence about it, Gore expressed, " We all know that generic drug product is approved by regulatory authorities (eg. in India - DCGI, USA - FDA) when it has met their standards with respect to quality, purity, potency, strength and identity. Cost is the main difference between the two."

It signifies the trust doctors have in regulatory authorities.

Conclusion

The generic manufacturer of eribulin will be conducting post marketing surveillance. Based on study reports quality of the generic drugs will be judged. However, with the launch of Eribilin, medical practitioners have an alternate to Halaven and can address the affordability factor making medication more accessible to more breast cancer patients.

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REPORT

Novartis' innovative gene therapy for spinal muscular atrophy gets stronger

The interim results demonstrated prolonged event-free survival in Type 1 SMA patients who received the therapy as well as achievement of milestone developments compared to the natural history of the disease, according to GlobalData

POSITIVE INTERIM results from a Phase III trial evaluating the effect of Novartis' Zolgensma in Type 1 SMA patients is expected to make the case stronger for its approval and also its long-term use as a mainstream treatment option, says GlobalData, a leading data and analytics company. While the company waits in anticipation for a decision on the approval of the drug, the latest results are not surprising. So strong were the results from the pivotal Phase I START trial that it was used as the basis for filing the drug for approval in US, Europe, and Japan. The interim results demonstrated prolonged event-free survival in Type 1 SMA patients who received the therapy as well as achievement of milestone developments compared to the natural history of the disease.

Due to the therapy being evaluated in a specific type of SMA patient population, in this case Type 1, the results are expected to provide impetus among physicians and patients for its long-term use in that particular patient population and avoid the risk of therapy not being favoured for use due to generalisation of safety and efficacy results to other patient populations that may not have been necessarily studied during the clinical trials. As promising as the results are, there are also concerns and unknowns of such therapies, for example, the long-term safety issues of introducing virus-based delivery platforms to deliver the gene therapy as well as the pricing of these therapies. Varkey concludes, "Results from ongoing clinical trials that evaluate these innovative therapies as well as collection of real-world evidence of patients who are expected to receive such therapies will help to clarify such issues and hence help in its wider adoption as mainstream option."

EP News Bureau

UPDATES

IVF tied to slight increased risk of rare childhood cancers

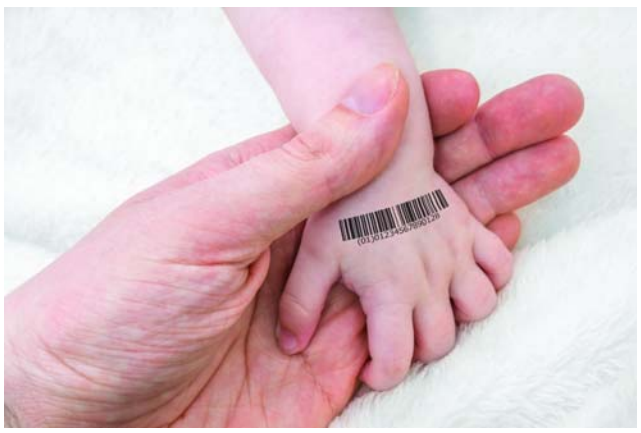
Kids conceived using IVF were 28 per cent more likely than other children to be diagnosed with embryonal tumours

"For the few cancers that seemed associated with IVF the absolute risk was still extremely rare," said lead study author Logan Spector of the University of Minnesota in Minneapolis.

The increased risk of cancer may be due at least in part to advanced maternal age and other health factors that lead women to try IVF in the first place, Spector and colleagues note in *JAMA Pediatrics*. While the results suggest it may make sense to be vigilant in monitoring IVF children for cancer, they don't mean couples shouldn't try to conceive this way, Spector said.

"There was no indication that any specific IVF procedure or treatment was associated with these cancers, so there is not really anything patients or their providers should be doing differently," Spector added. "Overall these results should be reassuring to parents who have used IVF."

Spector's team examined data on 275,686 children conceived with IVF and 2.27 million kids conceived naturally from 2004 to 2013.



They tracked children for an average of about four and a half years, during which time 321 cancers were detected among children conceived by IVF and 2,042 cancers were detected among other kids. That translates to a rate of 0.1 percent among IVF kids and 0.09 percent among naturally-conceived kids.

Put another way, if researchers tracked one million children for a year, they would expect to see one of these rare cancers develop in about 252 children conceived by IVF and about 193 kids conceived naturally.

Specifically, kids conceived using IVF were 28 per cent more likely than other children to be diagnosed with embryonal tumours, which develop from embryonic cells that remain in the body after birth. The increased risk of embryonal tumours was driven mostly by a higher rate of liver tumours. Kids conceived by IVF were more than twice as likely to have liver tumours than other children in the study.

Children conceived by IVF were also 41 per cent more likely to develop embryonal tumours of the central nervous system, which occur when embryonic cells remain in the brain after birth.

So-called germ cell tumours, or malignancies in the reproductive tissue like the testicles or ovaries, were more than twice as common with IVF. Overall, children conceived by IVF were 17 per cent more likely to develop cancer.

The study wasn't a controlled experiment designed to prove whether or how IVF might directly cause cancer. Researchers also didn't compare outcomes of infertile couples who used IVF to other infertile couples, making it difficult to see how the causes of infertility might influence the potential for rare childhood cancers.

It's possible that cancer can be caused by chromosomal abnormalities, said Dr Norbert Gleicher, medical director of the Center for Human Reproduction in New York City.

"As eggs age, chromosomal instability increases," Gleicher, who wasn't involved in the study, said by email. "This has been known for decades and is the cause for more chromosomally abnormal pregnancies and miscarriages with advancing age, but this chromosomal instability also leads to more mutations in various genes, many of which may be cancer causing."

Couples considering IVF shouldn't let the slight risk of childhood cancer influence their decisions, Gleicher advised.

"Having a doctor's visit is dangerous because one can be overrun by a car on the way, yet, we go to doctors all the time because the risk is very low and the potential gain by far exceeds the risk," Gleicher said. "The same principle applies here: there are risks in IVF but they are very low (as far as we can see so far) and, therefore, worth taking."

Reuters

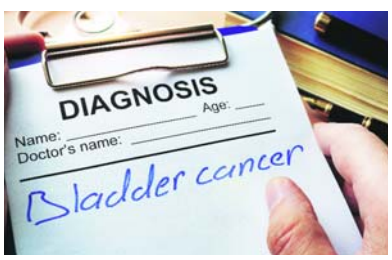
Clovis Oncology halts mid-stage bladder cancer trial

CLOVIS ONCOLOGY said it was halting a mid-stage trial testing its lead drug in bladder cancer patients, sending shares down 12 percent.

The company said its decision to discontinue the trial was based on recommendations of an independent committee, which suggested that the treatment may not provide a meaningful benefit to patients.

However, Clovis said it would continue to test the drug, Rubraca, in combination with other treatments for bladder cancer.

The drug is also being tested in late-stage trials as a treatment for ovarian cancer as well as for treating patients with prostate cancer.



Rubraca belongs to a new class of cancer drugs called PARP-inhibitors, which work by blocking enzymes involved in repairing damaged DNA of cancer cells, thereby helping to kill them.

Reuters

GSK wins US nod for two-drug HIV combination

GSK showed in drug trials last year that the once-a-day Dovato pill was as good as a standard three-drug cocktail in suppressing the virus that causes AIDS and also in terms of tolerability

GLAXOSMITHKLINE'S two-drug treatment for HIV infections won US market approval, boosting the British drugmaker's growth prospects against competitor Gilead Sciences. The US Food and Drug Administration cleared the combination of dolutegravir and lamivudine, to be branded as Dovato, for use in newly diagnosed adults.

GSK showed in drug trials last year that the once-a-day Dovato pill was as good as a standard three-drug cocktail in suppressing the virus that causes AIDS and also in terms of tolerability.

GSK's HIV drugs division ViiV, in which Pfizer and Shionogi & Co have small stakes, will use the lower drug burden as its main selling point to patients and physicians, while hoping that longer-term studies will yield hard evidence of fewer side effects over time.

As HIV positive patients grow older thanks to highly effective treatment, the focus shifts to long-term side effects as nearly half of all HIV patients in the profitable markets of North America and Europe are now over 50.

"We are trying to establish a new normal for people with HIV. We absolutely believe that people living with HIV should not take more medicines than they need," said Deborah Waterhouse, who heads the British drugmaker's HIV unit.

ViiV accounted for about 39 per cent of GSK's group operating profit last year, according to UBS analysts. With a 23 per cent share in the $26 billion-a-year HIV market, it is seeking to catch up with Gilead's 53 per cent.

Gilead will keep up the pressure with new anti-retroviral drug Biktarvy, a combination of three HIV medicines in a daily tablet, which was approved early last year. Market researcher Evaluate pharma expects sales from the product to reach $6.1 billion in 2024.

Hopes for growth — despite harsh competition from Gilead — rest on Dovato as well as on another two-drug combination that will be given as a monthly injection but regulatory approval of the latter is not expected before next year.

The company's growth prospects are clouded by the recent US launch of cheap generic copies of blockbuster asthma treatment Advair, generated 2.4 billion pounds in revenues for GSK last year.

GSK already has two-drug regimen Juluca on the market, but only for the smaller market of HIV patients that have received prior treatment. Dovato is the first such product for new cases.

Reuters

Second death in Novartis gene therapy trials under investigation

Novartis said investigation is underway into whether a second trial death could be related to its experimental gene therapy treatment, Zolgensma

NOVARTIS, WHICH announced positive interim trial results for its experimental gene therapy for spinal muscular atrophy, on Friday said investigation is underway into whether a second trial death could be related to the treatment.

Novartis has filed for U.S. Food and Drug Administration approval of the gene therapy, Zolgensma, and a decision is expected within weeks. The FDA submission was based on findings from a trial of 15 babies treated with Zolgensma.

But Novartis has expanded its clinical trial program – presenting on Tuesday at an Orlando, Florida meeting of the Muscular Dystrophy Association interim results for 22 babies with Type 1 SMA, the most serious form of the disease. The data showed that Zolgensma treatment resulted in encouraging progress in motor skills such as the ability to sit up. One patient died from respiratory failure, which was deemed by the investigator and an independent monitor to be unrelated to the gene therapy.

SMA, which can lead to paralysis, breathing difficulty and death, is the leading genetic cause of death in infants.

Novartis officials also disclosed that in addition to that death, a 6-month-old patient with Type 1 SMA had recently died after undergoing Zolgensma treatment in the company's European trial.

"Preliminary findings indicate this occurred in the context of a severe respiratory infection followed by neurological complications in a symptomatic SMA Type 1 patient, and was deemed possibly related to treatment by the investigator," Novartis spokesman Eric Althoff said.

He said an autopsy has been performed and results are pending. Meanwhile, trial investigators and regulatory authorities have been informed.

Gene therapies use engineered viruses to carry healthy genetic material into a person's cells to replace faulty or mutated genes that cause a disease or condition. Zolgensma

"As we learn more, we will provide further updates," Althoff said.

Novartis estimates that without treatment, 50 percent of babies with SMA Type 1 will not survive or will need permanent breathing support by the time they are 10.5 months old.

The company has said its price for Zolgensma will be determined in negotiations with health plans, but it believes the gene therapy would be cost effective at $4 million to $5 million as a one-time treatment.

Reuters

Merck's Keytruda wins FDA approval as combination therapy for kidney cancer

US FDA has given approval to Merck's cancer therapy, Keytruda, as part of a combination therapy for previously untreated patients with the most common type of kidney cancer

THE US Food and Drug Administration has approved Merck's cancer therapy, Keytruda, as part of a combination therapy for previously untreated patients with the most common type of kidney cancer, according to the company. The drug was approved in combination with Pfizer's Inlyta to treat advanced renal cell carcinoma. The approval, which comes two months ahead of expectations, allows this combination therapy to get an early launch ahead of other rival products, Cowen analyst Yaron Werber said, after the company received FDA approval recently.

The Keytruda/Inlyta combination could provide serious competition for Bristol-Myers Squibb's immunotherapy combination of Opdivo and Yervoy, currently considered a gold standard for previously untreated advanced kidney cancer patients.

Keytruda's sales have surged past Opdivo's, and the drug is expected to bring more than $10 billion for Merck this year, according to IBES data from Refinitiv. Merck's Keytruda, which works by increasing the ability of the patient's immune system to help detect and fight tumor cells, has been its most important revenue growth driver with its domination of the lucrative lung cancer space.

According to results from the study posted in February, about 90 per cent of the patients who received the Keytruda/Inlyta combination were alive after 12 months, compared with about 78 percent of patients who were alive after a year when treated with an older Pfizer standalone therapy Sutent.

Reuters

Lower dose of Pfizer-Lilly painkiller misses main goals in late stage study

A study, being carried out by the companies to test the effectiveness of lower doses of tanezumab for osteoarthritis, reported negative results

A LOWER dose of non-opioid painkiller developed by Pfizer and Eli Lilly and Company failed to meet main goals in a late-stage study in patients with moderate-to-severe osteoarthritis of the hip or knee, the companies said on Thursday.

The drug, tanezumab, belongs to a new category of pain medications that target nerve growth factor, a protein involved in the growth of nerve cells, and has been touted as a potential blockbuster.

The study tested the treatment in two doses, 2.5 mg and 5 mg, comparing the long-term joint safety and effectiveness at the end of 16 weeks with painkillers that are normally prescribed to patients.

The higher dose of the treatment met two of the three main goals, in which it reduced pain and improved physical function.

There were 10 deaths in the study, of which nine occurred in a group of patients who were given tanezumab. None were considered treatment-related, the companies said.

Reuters

VENDOR NEWS

Kilian teams up with Innojet and JRS to present new technologies for solids production

Kilian showed its STYL'ONE Evolution single-stroke press for research and development applications, which simulates standard tablet presses and carries out compression tests for developing new formulations or for scale-ups

Romaco Kilian recently teamed up with Innojet and JRS, their common partner, for two successful spring seminars. About 100 people from pharmaceutical, food, nutra and non-food sectors from Germany and all over Europe travelled to Cologne to attend expert lectures and workshops on the subject of granulation and tableting. Follow-up events are already in the pipeline.

Romaco Kilian recently teamed up with Innojet and JRS for the two latest seminars in the successful series launched at the end of 2016. The two two-day bilingual seminars provided an application-focussed mix of theory and practice. Introductions were followed with a quick rundown of their process solution portfolios for solids granulation and coating. A lecture on process optimisation in tablet production was next on the seminar agenda, which meant that many crucial details and key questions could be clarified right from the start. A short briefing by the speakers was followed by live demonstrations on the machines and a discussion round.

Kilian showed its STYL'ONE Evolution single-stroke press for research and development applications, which simulates standard tablet presses and carries out compression tests for developing new formulations or for scale-ups. The Kilian KTP 420X single-sided rotary press for pharmaceutical applications impresses with a maximum output of 360,000 tablets per hour and is among the high speed presses in its performance class. Innojet presented the Ventilus V 5 processing machine, which manages with just one product container for granulation, drying and coating on an air flow bed. JRS brought along its Vivacoat ready-to-use coating system and gave various demonstrations, including the correct way to prepare a coating suspension. This was followed up with a question and answe session with experts.

While touring the Romaco Kilian production and assembly shops, the seminar participants gained some fascinating insights into the tablet press maker's manufacturing processes. The visit to KiTech, Romaco Kilian's test laboratory, was one notable highlight. It offers interested users a chance to get to know the tradition-minded company's various technologies, optimise their existing tableting processes and try out new ones. Its comprehensive portfolio of services includes powder analyses, compression tests, feasibility studies and advice on scale-ups. Customers can also send their employees to KiTech for training. As a kind of light relief between the challenging stations, JRS had prepared a small, improvised "hand press": visitors were requested to fill it with granulate, which they then compressed into a tablet by hitting it with a hammer.

"The continuation of our seminar series with Romaco Innojet and our partner JRS was a resounding success," said host Matthias Weber, MD, Romaco Kilian, summing up. "Demand for the events was considerable and they were both fully booked. Our customers were treated to the complete solids spectrum, from process development through scale-up tests to the start of serial production."

EP News Bureau

Clariant MEVOPUR additive technology facilitates laser welding of medical devices

'Laser-friendly' masterbatches and compounds at MD&M West Medical-grade materials manufactured in ISO-13485-certified plant Systems approach ensures successful welding

CLARIANT, A leader in specialty chemicals, recently displayed medical devices and components made of new MEVOPUR polymer materials formulated to improve laser-welding performance at MD&M West 2019. The medical design and manufacturing tradeshow was held at Anaheim, CA.

"Laser welding is increasingly preferred in production of medical devices because it provides speed, and reliability, can handle complex structures and avoids some of the downsides of other methods, such as solvent residues," explains Eric Rohr, Medical & Pharmaceutical Segment Manager, North America. "However, because medical devices are frequently made of transparent or translucent materials, the polymer's ability to absorb the laser energy often needs to be enhanced using additives."

Clariant has offered such additives for many years, and in 2016 began using them in MEVOPUR masterbatches and compounds used in laser-marking applications. Welding presents additional challenges as laser marking involves only one polymer, while laser welding involves two : one that is transparent to the laser energy and the other absorbing energy to create the weld. The process is further complicated by any pigments or fillers, which can change the way the plastic reacts to the laser.

"For that reason, we take a 'systems approach' in our laser welding solutions," Rohr says. "At MD&M West, we will be displaying welded products that appear to involve two parts made of identical materials. In fact, we developed two different formulations to achieve laser transmission in one and absorption in the other so that they can be reliably welded together. Clariant's formulation experience and skills are the real key to success."

Another important factor in achieving a good weld is the even distribution of the additive throughout the polymer matrix of the final part. In some cases, a concentrate or masterbatch can be dosed at the injection-molding machine, which then mixes it sufficiently into the polymer melt before molding. Injection-molding machines, however, are not always ideal for dispersing the concentrate into the host polymer. In some applications, the machine, the material or the part design may cause inconsistent distribution and lead to unreliable welding.

Clariant solves this too by offering compounds where the job of distribution of the laser-absorbing additive, along with any other pigments or additives, is performed on highly efficient compounding lines. The injection molder then can use this all-in-one material without further dilution, knowing Clariant has already taken care of the formula and quality control.

Like all MEVOPUR masterbatch concentrates and finished compounds, the new laser-friendly materials are manufactured at a dedicated facility in Lewiston Maine, and at two other sites in Malmo, Sweden, and Singapore. All three plants have been certified compliant with ISO13485-2016, the latest quality management system for medical devices. As the three-year grace period comes to an end, all new device submissions must now prove certification to the 2016 standard. The MEVOPUR brand assures device manufacturers that, from USP Class VI, ISO10993 pretested raw material ingredients to final product, the Clariant processes are controlled, consistent and compliant.

MEVOPUR-brand products and services help medical device and pharmaceutical packaging producers minimise risk at every stage of design, production and approval. Clariant's global team of specialists from R&D, production, sales and marketing, and customer service, works closely with individual customers from the concept stage to production to pre-test materials and assess risk in order to develop compliant, targeted color and functionality for each application.

EP News Bureau

Honeywell introduces pharma packaging innovation in India with Aclar Accel

New, cost-effective barrier film addresses industry need for faster production and delivery

HONEYWELL HAS unveiled Aclar Accel, a new, cost-effective thermoformable barrier film for pharmaceutical packaging that provides faster service to companies at a lower cost while maintaining patient safety through increased protection for medicines. Aclar Accel, which expands Honeywell's line of Aclar films with two new gauges, was introduced at this year's Pharmapack Expo in Paris.

With two new clear and opaque laminated options for its high-moisture barrier films, Honeywell's Aclar gives companies cost-effective alternatives for product packaging with shorter lead times to increase shelf life, decrease operating costs and protect drugs in climates throughout the world. While the original Aclar is clear and customisable, Aclar Accel 1700 maintains the clarity, but has a standard size that allows for faster production and delivery to companies at a lower cost. Aclar Accel 5400 is designed for opaque laminates and offers an even denser, moisture-rich barrier to companies seeking a more cost-effective solution to protect drugs than cold form foil in aluminum blister packaging, which has higher production costs and slower output.

"Indian pharma companies have made rapid strides in developing new formulations and production techniques to conform to world standards. Companies are seeking new packaging technologies that allow them to get their drugs to market faster and reduce operational costs and Aclar Accel addresses those needs," said Rajarshi Datta, GM, Advanced Materials, Honeywell India. "Companies have trusted Aclar for more than 40 years to provide the highest quality protection for their drugs and Aclar Accel gives them new choices. Now, in addition to the customised options of the original Aclar, they can select standard sizes for packaging with these new films and receive them in half the time."In comparison to packages made of cold form foil, Aclar enables smaller blister pack sizes that reduce shelf space, usage of raw materials and lower transportation costs. Available in many thickness grades and a wide range of moisture barriers, Aclar provides flexibility to optimise moisture protection across different climate conditions.

EP News Bureau

PRODUCT

Special doors for clean rooms

GANDHI AUTOMATIONS offers a wide range of rapid roll high speed doors suitable for use in food processing, healthcare, leisure, pharmaceutical and research environments.

High standards of cleanliness are required in food manufacturing. High speed doors are suitable for all applications where food safety and cleanliness are crucial.

High-performance cleanroom doors with easily disinfected surfaces meet the most stringent hygienic requirements. Fast opening and closing and tight sealing minimise the spread of airborne particles and the risk of contamination.

The main entrance, infection clinic, surgery area, X-ray rooms, operating theatres, kitchen areas and emergency rooms all have entrances, but their demands differ. This is why every hospital and service residence require tailored solutions for each location. Gandhi Automations Prime Clean Reset provide added convenience, security and safety for staff, for people with mobility or sensory impairment, and most importantly – when saving seconds will save lives.

In a time of increased awareness of infectious disease and hazardous biological materials, the products help to maintain and increase the safety when isolating sensitive areas like surgeries, infection wards and the like. Quality automated entrance solutions can help reduce costs, save energy and prevent damage to doors and other equipment, while also improving internal logistics and generally making life easier for all users.

Strict legislation is enforced on medical facilities and hospitals with regards to frequent usage of doors. Rapid roll high speed doors assist in stopping the spreading of infections in hospitals, operating theatres, intensive care units, patient wards and X-ray rooms.

Doors within leisure centres, swimming pools and sports facilities need to cope with frequent usage while being hygienic at the same time. High speed doors are ideal for such use in leisure facilities as they are able to cope with high levels of traffic, while at the same time being hygienic, smooth and non-absorbent. They are resistant to heavy cleaning agents and are rust resistant in such high moisture environments.

Within pharmaceutical applications, research laboratories and cleanrooms, a high level of clean-ability and hygiene is required. High speed doors do not harbor bacteria, due to the smooth, seamless surfaces and non-porous qualities. The doors play a role in maintaining correct room pressures and air circulation rates.

A high degree of protection against intruding dust and other particles, very good values in air permeability, a material quality which guarantees minimum contamination, and a good visual and sound protection are key aspects for the chemical and the pharmaceutical industry. The special multiple seals and the high quality of materials in use (e.g. silicone-free) ensure that our industrial doors provide a protection equivalent to clean room applications.

Due to its design and high air tightness, the Prime Clean Reset is a standard door for compatible clean rooms. Like all high-speed doors by Gandhi Automations, the Prime Clean Reset clean room doors are enormously heavy-duty and require low maintenance thanks to their excellent quality. The powerful high-speed doors have a smooth surface structure and no protruding edges.

High-performance cleanroom doors by Gandhi Automations with easily disinfected surfaces meet the most stringent hygienic requirements. Fast opening and closing and tight sealing minimise the spread of airborne particles and the risk of contamination.

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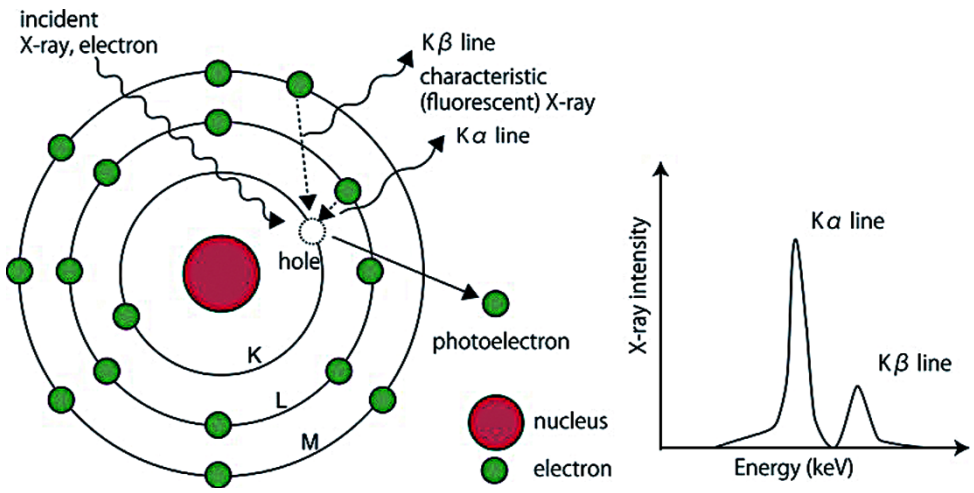
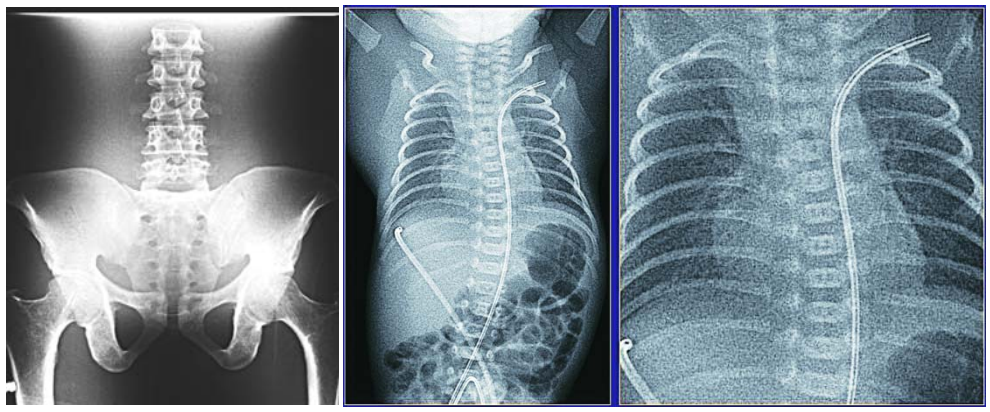
VALUE ADD

Radio-opaque silicon tube

Pritam Adhikary, Executive-R&D, Ami Polymer, discusses how the type and amount of radio-opaque filler compounded with silicone elastomer in the manufacturing of medical devices used in diagnostic radiology determines how they appear in X-ray scans

NOW A days silicone based biocompatible polymers are used to produce catheters and other devices that are inserted into the body for interventional procedures. Part inserted are commonly filled with substances opaque to X-rays, thereby rendering the devices visible under fluoroscopy or x-ray imaging. These fillers, or radiopacifiers are based on typically dense metal or metallic salt powders affect the energy attenuation of photons in an x-ray beam as it passes through matter, reducing the intensity of the photons by absorbing or defecting them. Because these materials exhibit a higher attenuation coefficient than soft tissue or bone, they appear lighter on a fluoroscope or x-ray film. This visibility provides idea about how to accurately position the device in the affected area. Image contrast and sharpness can be varied by the type and amount of radio pacifier used. Device design is also a factor like a higher loading of radiopaque material, for instance, is needed for thin-wall catheter tubing than for products with thicker walls. Generally, compounds should contain only the amount of additives absolutely required for the application, since overloading can result in the loss of the polymer's mechanical properties. Blending together several radiopaque materials can produce better results than using only one type in a formulation. Among the most widely used radio pacifiers for medical devices are barium sulfate, bismuth compounds, and tungsten metals that are excellent absorbers of x-rays. Selection of the correct fillers in the proper amount requires a thorough understanding of attenuation and how it is affected by various radiopaque compounds.





X-rays belong to electromagnetic radiations family having a range of wavelengths. Diagnostic X-rays fall near the shorter-wavelength end of the spectrum, measuring between 1 Å and 0.1 Å. X-rays are produced from the conversion of energy that results when fast-moving electrons from the element of an X-ray tube interacts with a tungsten anode or target. The kinetic energy of the electrons increases with voltage (Kvp). The intensity of an x-ray beam is determined by the number of photons in the beam and the energy of the photons in terms of Kev.

Material

Barium Sulfate

Barium sulfate (BaSO4) was the first radiopaque material to be widely compounded in medical formulations and is the most common filler used with medical-grade polymers. It is a non-harmful filler having specific gravity of 4.5. To optimise X-ray imaging during interventional procedure, normal doses are 20 to 40 PHR. Higher doses might destroy base polymer's physical properties.

Bismuth

Considerably more expensive than barium, Bismuth trioxide (Bi_2O_3), which is yellow in colour, has a specific gravity of 8.9. Since bismuth produces a brighter, sharper, higher-contrast image on an X-ray film than barium, it is commonly used where a high level of radiopacity is required.

Tungsten

It is a fine metal powder with a specific gravity of 19.35. Tungsten (W) is twice more dense than bismuth and can provide a high attenuation coefficient. Higher level of loading, up to 60 per cent, is possible for better attenuation and image contrast but beyond that, undesirable surface roughness occurs.

Medical devices used in diagnostic radiology must be easily seen on X-ray film and fluoroscopes in order for medical practitioners to precisely position them inside the body during critical procedures. The type and amount of radiopaque filler compounded with silicone elastomer in the manufacture of these devices determines how they appear.

Contact
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VALUE ADD

Why take preventive approach?

Shyam Padwal, Lead - Pharma Industry Vertical, B&R Industrial Automation, gives an insight on how technologies ensure to maintain optimal product quality, lower machine downtime, improve equipment reliability and increase overall efficiency

THE PHARMACEUTICAL industry is characterised by strong regulations and is obliged to deliver a product with defined quality to the consumer. Equipment plays a major role in influencing production quality and business efficiency. A breakdown could hamper drug quality and hence an organisation's competitiveness. Machine builders are deploying available technologies such as condition monitoring, remote monitoring and diagnostic for ensuring high machine availability with safety and security in pharma processing and packaging operations. In addition, these technologies ensure to maintain optimal product quality, lower machine downtime, improve equipment reliability and increase overall efficiency.

Shyam Padwal, Lead - Pharma Industry Vertical, B&R Industrial Automation

Importance of condition monitoring

"If it's not broken, don't fix it' still applies to many industries. However, the pharma industry cannot follow this technique as downtime impact both, product quality and the compliance with pharma processes. The success of an organisation heavily depends on production performance in terms of increased equipment and plant availability. This is feasible only by optimising and improving maintenance processes. Condition monitoring meets the requirement of the modern and competitive industry. It helps to maximise the effectiveness of equipment, a system or an entire plant. Properly planned and executed condition monitoring can help to minimise downtime, maximising equipment efficiency and reliability, reducing operating cost, improving equipment and operator safety, saving time among others. Condition monitoring assures machines and operator safety by highlighting possible issues even before they occur and result in downtime. In pharma manufacturing, a number of factors such as temperature rise, unknown vibrations, are responsible for wear and tear of machines. In addition, these machines are designed to perform continuous production, where stoppage, malfunctioning or breakdown of even a single machine can stop the entire plant, resulting in enormous material, production and quality loss. By using condition monitoring, manufacturers can monitor real-time status of a machine and plant, operational conditions, use historical data for comparison and analytics. A successful condition monitoring coupled with secure communication enables machine builders to monitor their assets 24/7. Based on condition data analytics, maintenance teams can predict possible failures and plan for necessary maintenance schedules without hampering production.

Risk assessment while implementing condition monitoring

Machines, devices, sensors, and workforce need to connect and communicate seamlessly with each other. One of the biggest obstacles in implementing data-driven monitoring such as condition, energy is making data flow from machines to ERP systems with a high level of security. It is important to protect machine data, production processes data, drug formulation information, which is companies' intellectual property. Breach of such data by any means will lead to financial damage; affect a company's reputation and overall stability. Given all of these factors, the IT department places a priority on data security, confidentiality and integrity above all.

Keeping track of your assets

Production heads in pharma production are all too familiar with the dilemma: How to improve product quality and increase system availability while at the same time cutting back on maintenance costs? B&R has an answer to this dilemma. B&R offers condition monitoring as a pre-installed, pre-configured package that makes implementing predictive maintenance more straightforward than ever. B&R's X20 module offers real-time status checks of machines, critical manufacturing assets, and utilities. It offers real-time insights of the health and efficiency of assets. With these modules, B&R has introduced onboard intelligence for vibration analysis that can make monitoring an integrated and standard feature in every machine. By maximising machine availability while minimising the time and money spent on maintenance, the X20 module allows significant reductions to the total cost of ownership of machines and systems. The condition parameters generated by this module not only provide operators with the information they need to optimise maintenance intervals but also are available for use directly as input in the automation software. An IEPE interface for querying acceleration sensors samples signals and processes them internally to generate more than 70 condition parameters, which are then transferred directly to the CPU via POWERLINK or any other standard fieldbus system.

In order to improve overall plants efficiency including auxiliary buildings, energy, and utilities, B&R also offers condition monitoring solution packages from APROL that reaches from the I/O level up to the process control system for the entire plant. B&R's APROL process control system makes it possible to unite plant systems centrally into a complete system using any conceivable hierarchy. With a broad spectrum of functions – including integrated system simulation using MATLAB/ Simulink – all levels of automation can be combined into a homogeneous system. With direct integration of external systems and signal sources, APROL allows an all-encompassing approach that ensures reliable and efficient operation of the system over its entire service life. Continuous condition monitoring increases the quality of products and the availability of machines and plants, while at the same

time reducing maintenance costs. B&R's APROL ConMon solution package provides vibration monitoring and analysis based on key condition parameters calculated from acquired measurement data. B&R condition monitoring solutions fit perfectly for a machine as well as factory automation.

Safety and security for production lines

Owing to proprietary protocols, seamless machine-to-machine communication and machine-to-IT communication inside a facility was uncommon and the topic of cybersecurity was not of great concern. However, things are changing with the increasing use of new technology opening up potential targets for hackers. B&R has introduced the SiteManager for balancing the needs of production and IT with enhanced security. The device has an integrated firewall and takes care of cybersecurity. Having the SiteManager between the controller and the Internet/cloud ensures that any data transferred between the machine and applications outside of the company network is protected against unauthorised access. To transfer data to the cloud, the controller connects with the SiteManager via OPC UA and is capable of transmitting this to the upper layers via MQTT. OPC Unified Architecture (OPC UA) is a vendor-independent communication protocol for industrial automation applications. OPC UA bridges the gap between the IP-based world of IT and the production floor. It is based on the client-server principle and allows seamless communication from the individual sensors and actuators up to the ERP system or the cloud. The protocol is platform-independent and features built-in safety mechanisms. Since OPC UA is flexible and completely independent, it is regarded as the ideal communication protocol for the implementation of Industry 4.0. B&R relies on open source communication such as OPC UA and is an active member of the OPC Foundation participating in various working groups.

B&R's X20 module for condition monitoring is a snap to integrate into an overall automation solution – no expertise in vibration mechanics required!

The APROL process control system from B&R and the individual APROL ConMon solution is extremely effective at further increasing pharma production efficiency

"Pharmaceutical machine builders and facilities are swiftly recognising the vast benefits offered by these solutions. They are increasingly turning to make their machines and facilities efficient with lower downtimes. Condition monitoring together with data logging enables them in their endeavour to be competitive," explains B&R's Lead - pharma industry vertical, Shyam Padwal.

B&R presents ultra-thin power panels for swing arm systems

B&R OFFERS its power panel operator panels for swing arm mounting. The compact terminals feature all-round IP67 protection and are perfectly suited for use right at the machine. The devices are available in widescreen format in five sizes from 5.0" to 21.5". With an embedded browser, Power Panel T50 Field HMI terminals are well-suited for displaying web-based HMI applications with mapp View.

The devices are either 16.5 or 26 mm deep, depending on the display diagonal, and designed for mounting on a swing arm, where they can be easily swiveled into the operator's preferred position. The Power Panels can also be installed on VESA mounting units. The FT50 terminals have a Power over Ethernet (PoE) connection, which means only a single cable provides both power supply and network communication.

Easy operation

Power panels are easy to configure and perfectly complement a high-end machine design. The multi-touch technology makes it possible to integrate commonly used gestures like swiping and zooming for intuitive, clearly structured user guidance. The projected capacitive touch screen responds precisely and reliably, even when operated while wearing thick leather gloves.

The right info at the right time

With a Power Panel FT50 running a web-based mapp View HMI application, operators have access to the information they need, when and where they need it. mapp View allows automation engineers to create easy-to-use HMI solutions without any background in HTML5, CSS or JavaScript programming. With just a few clicks they can set up features like two-hand confirmation for critical operations.

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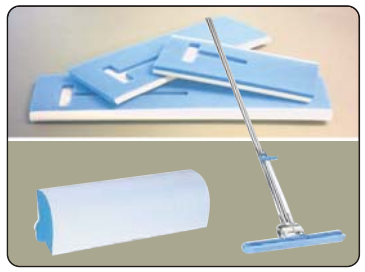
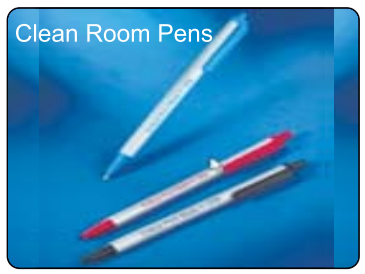
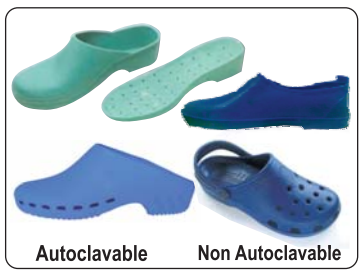


Clean Room Mopping Systems

Rust Removal System

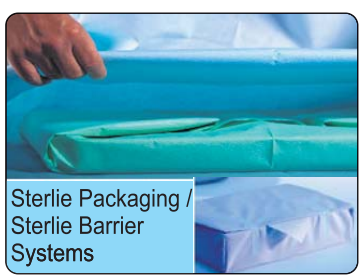


Clean Room Stationery



Clean Room Shoes

Autoclavable Goggles

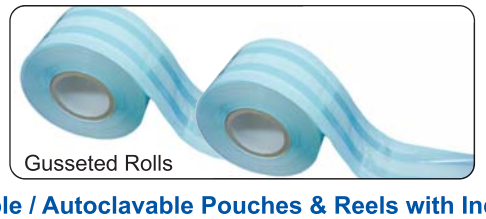


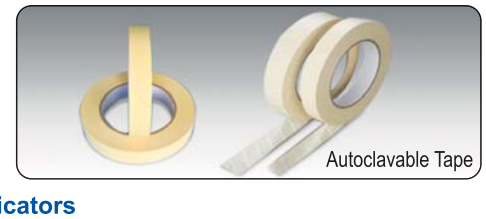
Sterlie Packaging

Clean Room Wipes

Fogger for Fumigation

Autoclavable Clean Room Trolley Systems: Plastic & Stainless Steel





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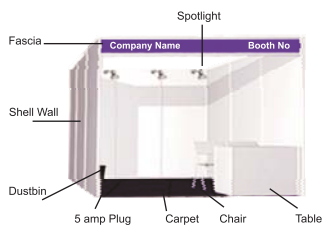

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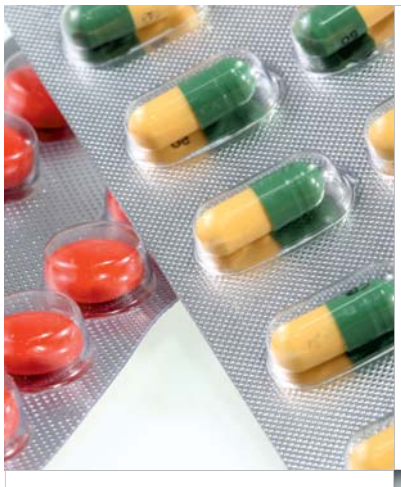
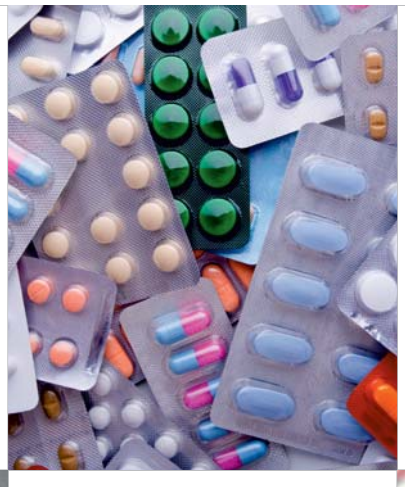


PVC RIGID FILM FOR BLISTER FORMING

US FDA Type III
DMF: 032495



TRIPLEX LAMINATE

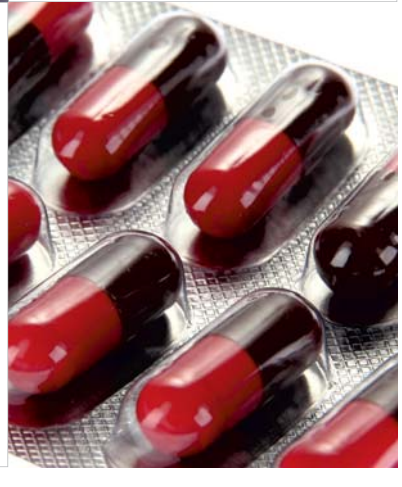
US FDA Type III
DMF: 032497

ALU ALU LAMINATE

US FDA Type III
DMF: 032494

PVdC COATED PVC FILM

US FDA Type III
DMF: 032496



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2019 Highlights

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- **1000+** buyer seller meetings
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2018 Glimpses

Exhibitor Profile

- Pharma Processing Machineries
- Environment Control Equipment & Services
- API Bulk Drugs
- Research Organisations
- Water Treatment Plants
- Utilities Products & Services
- Bulk Drug Manufacturing
- Pharma Finished Products
- Packaging Machineries, packaging materials & Consumables

Visitor Profile

- CEO & Top Management
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APPOINTMENTS

Sanjay Murdeshwar of AstraZeneca chosen by Novartis to lead its India business

Sanjay Murdeshwar, currently the Global Vice President, Cardio-Renal business at AstraZeneca, has been picked by the Swiss company to head its business in India

Novartis has appointed the current Global Vice President, Cardio-Renal business at AstraZeneca, Sanjay Murdeshwar, to lead its business in India. Murdeshwar has earlier also been the India head of AstraZeneca for the period of 2013-2017.

Previously, two new appointees to the position left the Novartis in a span of two years.

With sales over Rs 1400 crores, business in India for Novartis is primarily driven by its portfolio of anti-diabetic drug. The company is currently being examined by Competition Commission of India after it allegedly connived with Abbott to fix the price of its anti-diabetic drug. The two companies were sent show cause notices by CCI after an informant approached the anti-trust authorities claiming collusion.

EP News Bureau

Cipla appoints Dr Raju Mistry as President and GCPO

In her role at Cipla, Mistry will oversee human resources, and administration and facilities management

CIPLA ANNOUNCED the appointment of Dr Raju Mistry as President and Global Chief People Officer (GCPO) of Cipla. Mistry is an accomplished and veteran Human Resources (HR) leader with over 27 years of global experience across diverse sectors such as Chemicals, Pharma, FMCG, IT, Engineering and Textiles. Prior to joining Cipla, Mistry was Chief Human Resources Officer (CHRO) at Jubilant Life Sciences. For 13 years before that, Mistry led the talent, employer brand and leadership programmes of the Aditya Birla Group, and was CHRO of Grasim's Pulp and Fibre business. She has previously worked with Tata Sons, Colgate Palmolive, Siemens, and Mastech Corporation, Canada.

In her role at Cipla, Mistry will oversee human resources, and administration and facilities management. She will be a member of the Management Council of Cipla, and will report to Umang Vohra, Managing Director & Global Chief Executive Officer.

Commenting on the appointment, Umang Vohra, MD & Global CEO, Cipla said, "We are delighted to welcome Mistry to the Cipla family. In the last few years, Cipla has successfully worked towards strengthening its core, reiterating its values and focussing on building a future-ready organisation. Mistry brings with her the experience to continue the journey and help us reach new milestones."

EP News Bureau

CAMPUS BEAT

Lloyd Group of Institutions organises Niyukti Job Fest in Noida

More than 1700 students from 230+ institutes/universities registers for the placement drive conducted by 50+ companies

LLOYD GROUP recently organised Niyukti-2019 — 4th mega Job Fest, in association with Indian Pharmaceutical Association (IPA) for the pharmacy and management students wherein students from across India participated. Leading brands from different sectors like production, quality assurance, quality control, sales and marketing, business development, banking and finance, human resources, R&D, regulatory affairs etc, were invited to be a part of this event.

More than 1700 students from 230+ institutes/universities registered for the placement drive conducted by 50+ companies. The valedictory ceremony was graced by eminent dignitaries like Dr GN Singh, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission; Prof RK Goyal, Vice Chancellor, DPSRU; SL Nasa, Registrar, Delhi Pharmacy Council; Prof Roop K Khar, Former President, Indian Pharmaceutical Association; Dr Raman Dang, Registrar, DPSRU; Dr Farhan Jalees, Dean — Interdisciplinary Technology, Jamia Hamdard and Dr Gaurav Jain, Secretary, IPA, Delhi. The Chief Guest, Dr S Eswara Reddy, DCG(I) sent a short video in lieu of his unavailability for the event. Lloyd's bi-annual newsletter was also released during the event.

Students from leading institutes like Delhi University (DIPSAR), Jamia Hamdard, AIIMS, Amity University, BHU Institute of Medical Sciences, Banasthali Vidyapeeth, BITS, Chitkara University, DPSRU, Guru Jambeshwar University (Hisar), DIT (Dehradun), Dr Harisingh Gour Central University Sagar, GLA University, Galgotia's University, GD Goenka University, Jaipur National University, JSS College of Pharmacy, KR Mangalam University, KIET (Muradnagar), Kurukshetra University, MIET (Meerut), NIPER, RKGIT (Ghaziabad), Sharda University, Uttarakhand Technical University, Subharti University and Teerthankar Mahaveer University participated at the fest.

Many celebrated brands such as Cipla, GlaxoSmithKline, Torrent Pharmaceuticals, Apollo Hospitals, AIMIL, Akums, Alembic, Alkem Laboratories, Arbro Pharmaceuticals, Belco Pharma, Blueocean, Florencia Healthcare, Florencia Healthcare, Hetro Drugs, Intas, Knoll Healthcare, Mascot Healthseries, Nutrilife, ORN Remedies, Raptakos, Sastasunder Healthbuddy, Systopic, Turacoz, Vissco, Zuche Pharmaceuticals, Axis Bank, Varahi, Big Basket, 10times, Spectrum Talent Management, Art Housing Finance, Myndtree Business Service, Team Lease, Yo Multinational, Qualtechpro, Vishwa Laxmi Food & Beverages, Acuité, Petpooja, Paytm and Nerdy-turtles were also a part of the fest.

Lloyd Job Fest is sumptuously publicised, covering a huge geographical arch and attracts students from not just Uttar Pradesh and Delhi-NCR, but also from Rajasthan, Odisha, Maharashtra, Tamil Nadu, Madhya Pradesh and Punjab. It began in 2016 out of a discussion among the Group Chairman, Manohar Thairani; former Drug Controller General (India) Dr G N Singh; SL Nasa, Registrar, Delhi Pharmacy Council and President, Indian Hospital Pharmacists' Association and the person bringing all of them together, Lloyd Group Director, Prof (Dr) Vandana Arora Sethi. Since its inception, Niyukti has hosted more than 4000 students and 150 recruiters in its campus, with about 1700 students founding their first job.

Established in 2004, Lloyd Group of Institutions currently offers courses ranging from diploma, degree, to post graduation in pharmacy, management, data analytics, education and law. All the courses are duly approved by their respective regulatory agencies and over the years have gained prestige for their quality and the holistic learning experience gained by students on the campus. A testimony to the quality of education offered is that the B Pharm programme of the institute has been recently approved for accreditation by the National Board of Accreditation (NBA), which ensures implementation of international quality standards and relevance of technical education.

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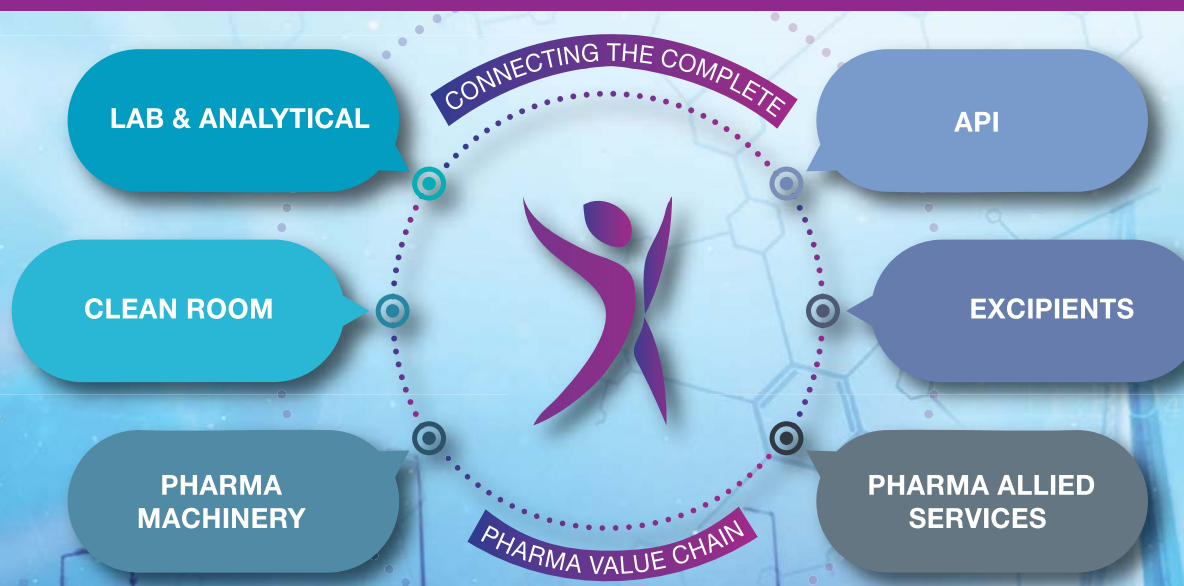
- NEW ARRIVAL — API and Excipients pavilion
- Pre-fixed B2B meetings

and many more...



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