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NEWS LETTER
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Lords To Investigate Private Health Firms Used To Deliver NHS Drugs

Peers are launching an inquiry into private health companies paid millions of pounds to courier NHS medicines in England, after the Guardian exposed how sick children and adults were being harmed by botched, delayed or missed deliveries. The House of Lords public services committee will examine "the extent of the problems in homecare medicine services", and the impact on patients, clinicians and the wider health service. More than 500,000 patients and their families rely on private companies contracted by the NHS to deliver essential medical supplies and care to their homes.

A Guardian investigation revealed how Sciensus, Britain's biggest provider of homecare medicines services, has struggled to provide a safe or reliable service. Seriously ill children as young as four have been let down, with some becoming sicker because of failings by the company. Patients and medics have complained to Sciensus and to regulators, but little has changed. Estelle Morris, the chair of the committee, said: "There are reports of missed deliveries, delays, and potentially significant health impacts for patients. Our inquiry will seek to examine how far these problems are occurring and the impact of these problems – both for individuals and the wider NHS."

Announcing details of the inquiry, which will begin on Wednesday, Lady Morris added: "The government is increasingly focused on how to treat more people out of hospital and look after them in the community. Homecare medicine services could form part of the answer to this, and it is crucial that they – and the system – can be relied upon to give patients the care they need, when they need it. We have received feedback that this may not be the case at the moment.

"The services we will be looking at are private companies, which have a sometimes arms-length relationship with the NHS. We are looking at how they are governed, managed, and how standards are enforced. We will also examine transparency and accountability – someone has to take responsibility for getting this right."
Sarah Sleet, the chief executive of Crohn's & Colitis UK, a charity asked to give evidence to the committee, said she was "delighted" by the launch of the inquiry. "We are grateful that the Guardian's important investigative journalism has brought this issue to the fore. Patients deserve better and we hope this inquiry can bring about real change. We need all patients – whoever and wherever they are – to get a good quality service so that they can get on with treatment as their healthcare team has set out."

Johnbosco Nwogbo, the lead campaigner of We Own It, a campaign group, said the launch of the inquiry was "brilliant news", adding that it came after "really important work from the Guardian". "Finally, we're starting to see action on the truly appalling treatment of vulnerable patients by private company Sciensus. No one should be left in the lurch without the medication they need. "The Guardian played a vital role in bringing this about by shining light on the stories of patients who were fobbed off for months by Sciensus. We hope that this inquiry is only the first step in a series of decisive actions by parliament to clamp down on the conduct of this company and others like them."

Sciensus, in previous statements to the Guardian, has repeatedly said it knew how important it was for people to get their medicine on time. It said it had a range of support services to help patients, including a priority helpline and same-day emergency dispensing and delivery. ...as you're joining us today from India, we have a small favour to ask. The Guardian has spent the past 13 years tirelessly investigating the shortcomings of the British Conservative government - austerity, Brexit, partygate, cronyism, the Liz Truss debacle and the individual failings of ministers who behave as if the rules don't apply to them. Our work has resulted in resignations, apologies and policy corrections. And with an election just round the corner, we won't stop now. It's crucial that we can all make informed decisions about who is best to lead the UK. Will you invest in the Guardian this year? Unlike many others, the Guardian has no shareholders and no billionaire owner. Just the determination and passion to deliver high-impact global reporting, always free from commercial or political influence. Reporting like this is vital for democracy, for fairness and to demand better from the powerful.

And we provide all this for free, for everyone to read. We do this because we believe in information equality. Greater numbers of people can keep track of the events shaping our world, understand their impact on people and communities, and become inspired to take meaningful action. Millions can benefit from open access to quality, truthful news, regardless of their ability to pay for it. (Source: The Guardian)

Indian Government Moots Single Regulatory Portal for Drugs

The Health Ministry is planning a unified portal for digital drug regulatory mechanism. The portal will include the details of stakeholders, such as manufacturers, distributors, and procurement agencies, among others. Components of the Digital Regulatory System, according to the draft document, will include a single window / dashboard; a mobile application; alerts and delivery notifications across different messaging platforms via e-mail or SMS; chatbots and a dashboard with access to the Central Drugs Standard Control Organisation (CDSCO) and other authorities.

The portal will also integrate other existing IT portals of the CDSCO, including Sugam (an online licensing division), MD online (granting licences for manufacturing and import of medical devices and in-vitro diagnosis devices), Sugam Labs (lab information management system), Online National Drug Licensing System for State authorities (ONLDS), and Import Clearance Sytem (ICS). "These platforms have been developed and implemented by the CDSCO over a period of time. They operate through separate domain name and are not easily accessible, and their performance has often been slow.

They are also not able to handle peak time demand most of the time. Integration of data with other government agencies, or in-built checking system are also not up to the mark. Hence, there is a proposal to integrate it all into a single digital regulatory system," an official aware of the discussion, told businessline.

The revamped system will have the databases of manufacturers, recipients, and marketers, among others; database of consumption patterns, including area-wise sales and seasonal trends; maintaining data of adulterated or spurious products; and a complaint and redress mechanism for users; among other factors. The portal will be hosted through a MEITY-empanelled cloud service provider, and it will be integrated with Central agencies such as PAN, Aadhar, DGFT and Customs.

Provisions for stricter regulation comes in the wakes of India pharma companies, particularly cough syrup makers, drawing flak for alleged deaths of children in places like Gambia and Uzbekistan. Investigations by India too had revealed that there were violations in good manufacturing practices in some cases. India will also consider a new drugs Bill during the upcoming Monsoon session of the Parliament.

The Drugs, Medical Devices and Cosmetics Bill 2023 reportedly is awaiting Cabinet approval, and which will replace an earlier drugs law, The Drugs and Cosmetics Act, 1940 – a pre-Independence era legislation. "The bill seeks to regulate the import, manufacture, distribution and sale of drugs, medical devices and cosmetics....clinical investigation of medical devices and clinical performance evaluation of new in-vitro diagnostic medical device...," those aware said. The Bill also proposes regulation of traditional medicines. (Source: Business Line)

India's Pharma Exports Grew By 5% In April – May.

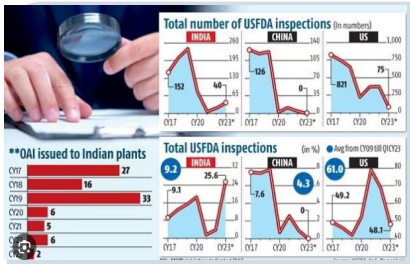
Drug exports continue to be on the rise, despite instances of some desi pharmaceutical companies recalling their products from the US and reports of deaths in Gambia and Uzbekistan allegedly linked to cough syrups made in India last year. The pharmaceutical exports from the country recorded a 5% increase during April and May this year over the corresponding period in 2022.

S V Veeramani, chairman, of the Pharmaceuticals Export Promotion Council of India (Pharmexcil), set up by the Union Ministry of Commerce and industry said, India recorded pharmaceutical exports to the tune of $4.3 billion in April and May this year. "While there was a decline in exports of several commodities, the pharmaceutical exports have gone up 5% when compared with the corresponding period last year. While the US, which is the top market for India and accounts for more than 30% of our total pharmaceutical exports, there is a 10% growth, Europe also witnessed good growth. This is a testimony that the Indian pharmaceutical is not affected due to a couple of instances," he told TOI. He was speaking on the sidelines of 'Pharmac South 2023', a pharmaceutical expo inaugurated here on Friday.

India's share in the global pharmaceutical export market is 10% by volume. Known as the pharmacy of the world, India is home to 7,000 pharmaceutical units. Of these, 2,000 units have WHO's Good Manufacturing Practices certification, 700 are US Food and Drug Administration-approved facilities, and 600 are approved by European countries. The Indian pharmaceutical market was at $50 billion in FY23. While exports accounted for $25.4 billion, the rest is catered to the domestic market.

"We are expecting around 10% growth this year," Veeramani added. Daara B Patel, secretary general of, Indian Drug Manufacturers' Association (IDMA) said, India caters to almost 200 countries in the world. "What has happened is unfortunate. But I do not think that the industry will have a setback for the simple reason that the industry is very large in India," he said, responding to a query on the impact on the pharmaceutical sector due to past instances. (Source: Times of India)

USFDA Inspections Of Indian Pharma Sites Gain Pace



In a trend that could augur well for the Indian pharma industry, inspections of manufacturing sites by the US Food and Drug Administration (USFDA) have gained pace. "In the last four months, there has been a perceptible spurt in the number of inspections, and the agency has also hastened the process of post-inspection procedures," a senior director with a Hyderabad-based listed drug major told businessline.

This is evident from the number of Establishment Inspections Reports (EIRs) being received by pharmaceutical manufacturers of late. About a dozen Indian drug-makers, including Aurobindo Pharma, Lupin, Alembic, Laurus Labs, and Natco Pharma, have received EIRs from the USFDA in recent months.

According to industry sources, few major drug makers have been investing in setting up new facilities in the post-pandemic phase, which are in various stages of completion. Speedy inspections would also augur well for the new facilities. India has about 670 USFDA-approved manufacturing facilities in India, the highest outside the US. After a break due to Covid, FDA resumed its inspections on a low scale early 2021.

"The feedback from our members point out to an increased traction in the inspections which is a welcome development. We hope this would reach the pre-pandemic levels soon," said R Uday Bhaskar, Director General, Pharmaceuticals Export Promotion Council (Pharmexcil). The increased pace of inspections by the US regulator is seen as a greater push to the Indian pharma industry, as it will lead to more product filings for approval and, thereby, higher exports. The US market has a lion's share of about 32 per cent in the total drug exports of the country. And they are increasing. In the April-May period of FY24, exports to the US grew by 10.4 per cent at $1376 million compared to $1245 million same period last year, according to Pharmexcil data. (Source: Business Line)

Pharma Companies See Decade-High Success Rates in USFDA Audits

Despite the US market accounting for a third of revenues, Indian pharma companies have not experienced an increase in favourable outcomes from USFDA audits. But this could be changing. In the first half of 2023, about 93 per cent favourable outcomes have emerged, on a base of 94 visits. This ratio averaged at 83 per cent in the last decade. USFDA audits typically result in either favourable outcomes NAI (No action indicated) and VAI (Voluntary action indicated) or an unfavourable outcome-OAI (Official action indicated), which is later followed by warning letter.

A portion of Nifty Pharma's 15 per cent recovery YTD can be attributed to lower overhang of plant issues impeding launch plans. Even recent stock returns point to a period of improved expectations on this front. Nifty Pharma, after the post-Covid run-up, declined 20 per cent from October 2021 peaks to December 2022 low and thereafter, has recovered 15 per cent to date. A portion of the recovery can be attributed to lower overhang of plant issues impeding launch plans, driving earnings or multiple expansion. That said, the compliance rate in India has room for improvement. USFDA inspections in the US in the last five years average at 2,400 per year, with a favourable outcome ratio of 96 per cent.

Who's improved?

Currently, Aurobindo Pharma joins Dr. Reddy's and Zydus Lifesciences in reporting better compliance record. During 2020-22, Aurobindo facilities witnessed two warning letters, several OAIs and 10 to 14 observations per visit. However, as of Q4FY23, one API unit (out f eight) of Aurobindo had received a warning letter, and all eleven of its formulation units received a VAI classification. But with a wide array of plants, Aurobindo's compliance risk remains. A recent inspection of the API unit in Anakapalli resulted in four fresh observations and remains to be seen how it may be classified by US FDA.

Zydus Lifesciences ' nil observations at Ahmedabad this year and a VAI classification for Moraiya last year significantly decreases compliance risk. Previously, a warning letter to Moraiya in 2019 resulted in launches being held back. Similarly, for Dr Reddy's , frequent compliance failure at the Srikakulam and Duvvada units had impacted launch plans for more than three years for the company. Both the facilities have been clear in the last one year. Assuming a 2-year inspection frequency mandated by the FDA, the recent clearance paves way for reduced compliance risks in the medium-term for facilities that have been cleared.With a 2-year inspection frequency for FDA, the fresh clearance paves way for lower compliance risk in medium-term for cleared facilities.
However, other players have not had it easy.

Overhang for some

Sun Pharma's Halol unit received import alert early this year and a temporary halt in exports to the US from Mohali (acquired as part of Ranbaxy acquisition). The company's shift to specialty revenues though, limits the impact of such classification for Sun as it moves away from generic production. Lupin reported six favourable outcomes in the last two years. But with its key plants under the lens currently, the impact on operations will be significant. Pithampur (10 observations in March 2023), Manideep (8 observations in November 2022), and Tarapur (warning letter in September 2022) will also cost the company more than ₹150 crore a year in remediation related costs which can be contained significantly on clearance. Cipla's gAdvair, which should net the company more than $30-50 million per year, may be held back till it clears observations received in February on its Pithampur unit (eight). Its Goa plant, which has an OAI status, doesn't help either. Glenmark Pharma reported three warning letters in the last nine months for Baddi , Monroe and Goa plants, making US recovery an uphill task. These companies have made investments to keep up with evolving USFDA standards. Plant restructuring to overcome Nitrosamine impurities is an indicator. But with a strategy that is heavily invested in the US, compliance track record should elevate to consistently higher levels for all companies. (Source: Business Line)

Pfizer Scraps One Weight Loss Drug In Race To Develop Ozempic Rival

Pfizer Inc (PFE.N) said it is scrapping its once-a-day experimental obesity pill because of concerns about liver safety, but will continue developing its other obesity pill, the twice daily treatment danuglipron, as it races to rival the success of other weight loss treatments. The company's shares fell more than 5% in early trading on Monday as Pfizer said it would stop developing its therapy lotiglipron after patients who took the drug in clinical studies were shown to have elevated levels of liver enzymes.

Pfizer CEO Albert Bourla has said an obesity pill could eventually be a $10-billion-a-year product for Pfizer. The company's shares have dropped around 29% so far this year as it works to develop its strategy past the COVID vaccines and therapeutics that drove revenue and earnings for the past few years. The NYSE Arca Pharmaceutical index, which tracks drugmakers, is down around 1% over the same period.

The company said it expects to finalize plans for the danuglipron late-stage program by the end of the year, and is also developing a once-daily, modified release version of that drug. Pfizer has been developing both pills in parallel, but had said all things being equal its preference would be for the once daily lotiglipron.

The news comes days after competitor Eli Lilly (LLY.N) released promising data for its own once-daily experimental pill, orforglipron. Truist Securities analyst Robyn Karnauskas said Lilly is now ahead in the race for a once-a-day obesity pill. "We believe while (twice a day) has advantages, we really need a (once daily) formulation for weight loss," she said in a research note. Pfizer said last month that danuglipron helped patients lose weight on par with Novo Nordisk's (NOVOb.CO) Ozempic in a mid-stage study that tested it in patients with Type 2 diabetes. (Source: Reuters)

Pfizer's $43 Billion Seagen Takeover Faces EU Investigation

Pfizer Inc.'s proposed $43 billion takeover of Seagen Inc. will face an investigation from the European Union's merger enforcer as the bloc continues to scrutinize large biotechnology deals. Seagen disclosed in a regulatory filing late Friday that both firms have referred the deal to the European Commission, and the EU executive has accepted jurisdiction for investigating the proposal. The filings say that EU approval is a condition for the deal to close.

In the United States, the Federal Trade Commission will subject the proposed merger to an in-depth antitrust review, as is normal for major deals. The companies said when the takeover was announced that they expected close FTC scrutiny. Pfizer announced in March that it would buy the Bothell, Washington-based cancer-drug maker as a way to move out of pandemic mode. Seagen is a leader in developing a type of medicine called antibody-drug conjugates, which use antibodies to deposit a strong concentration of drug directly at a tumor site — an effort to increase efficacy with fewer side effects. If the takeover goes through, Seagen's portfolio would double Pfizer's pipeline of early-stage experimental cancer therapies, Pfizer has said.

Notice of the investigation comes as the EU continues to heavily scrutinize large biotech deals. This week, the bloc hit DNA-sequencing giant Illumina Inc. with a €432 million ($476 million) fine for pushing through its $7 billion acquisition of cancer-test provider Grail Inc. without first obtaining regulatory approval. A divestiture order in that takeover is likely to be issued by EU regulators later this year (Source: Business Line)

Samsung Biologics Unveils $920 Mln Manufacturing Deals For Pfizer

South Korea's Samsung Biologics (207940.KS) announced on Tuesday two deals with Pfizer (PFE.N) worth around a combined 1.2 trillion won ($921.38 million) to manufacture products for the U.S. pharmaceutical giant.

The latest deals will see the biotech division of the Samsung Group produce biosimilar products ranging from oncology and inflammation to immunotherapy in the period to 2029 at its new Plant 4 in South Korea.

The latest orders bring this year's combined tally of orders from Pfizer to $1.08 billion, Samsung Biologics said in a statement.

Tuesday's announcements include a 922.7 billion won contract, as well as an additional 254.3 billion won order that is a follow-up to a deal previously announced in March.

Samsung Biologics welcomed the orders as an expansion of a strategic partnership, adding that it had won total contracts worth 1.93 trillion won so far this year, surpassing last year's annual contract volume. Earlier this year, Samsung Biologics signed deals with Eli Lilly Kinsale and GlaxoSmithKline (GLAX.NS). (Source: Reuters)