REVA Pharma
Caring for Healthier Lives

NEWS LETTER
For Private Circulation only

The Guardian View On India-UK Trade Talks: Don't Make It Harder For The Health Service

India is known as the "pharmacy of the world", supplying vital generic medicines at low prices to health services including the NHS. You'd think it would be in the interest of the UK government to keep it that way. Yet, as campaigners writing to the Guardian last month pointed out, a trade deal nearing completion with India could take a wrecking ball to that arrangement – cheered on by big pharma, which stands to profit.

It's about patents, a once-dusty subject that has become a life-and-death issue. Put simply, pharmaceutical companies that invent a new medicine are entitled to a patent on it in the US, UK and Europe lasting up to 20 years, allowing them a monopoly on sales at high prices. They spend billions on research and recoup billions. That's the bargain. Once the patent has expired, generics companies can copy the drug, competing to sell it at affordable prices.

But India, which only began to recognise drug patents after joining the World Trade Organization in 1995, still has some different rules. An important one is that public health – the need of the sick for a medicine – can trump the interests of the company making a patent claim, leading to it being refused.

This is one of the provisions the UK is gunning for in its free trade agreement negotiations, which have seen 14 rounds of talks. London also wants the inventor companies to be allowed to extend or renew their patents, with a modification tweak here or a minor reformulation there. It's a practice familiar to wealthy countries, known as evergreening. The UK also wants India to abolish the right of NGOs or doctors to challenge a patent before it is granted. India's patent-busting has saved countless lives: it was the influx of the country's affordable generics that drove down the price of HIV treatment from more than $10,000 to less than $100 a year.

Patent-lengthening on important medicines is hard to defend. The US writer John Green took up the cause of bedaquiline, a rare and important new antibiotic against multi-drug-resistant TB. Johnson & Johnson (J&J), which invented it – all credit to them – revealed that they planned to renew their patent on bedaquiline when it expired last year. Mr Green mobilised his substantial online following to petition J&J and tell everyone they know that the company's actions were immoral and bad business, naming a lot of the company's widely sold brands. Within days, J&J backed down.

The hand of big pharma has been detected in the FTA discussions. The UK is headquarters to AstraZeneca and GlaxoSmithKline, which employ thousands of well-paid people. The proposals will enhance their bottom lines. No doubt that explains why the EU takes the same hardline approach in trade talks with Delhi.

If western nations get their way, however, it would mean a higher NHS drugs bill. A quarter of NHS medicines are cheap generics made in India. We will be paying high prices for extra years before the generic equivalents come online, surely robbing Peter to pay Paul. When leading charities warned last November that tightening IP laws would be bad for India and bad for the NHS, a government spokesperson said ministers only wanted to strike "a balance between encouraging innovation and ensuring access to affordable medicines". But what is being proposed would, it seems, tip the scales too far towards profits – and away from patients. (Source: The Guardian)

Lupin Reports Three USFDA Approvals In Less Than a Week

The US Food and Drug Administration has approved Propranolol Hydrochloride Extended-Release Capsules (the generic version of Inderal sold by Minnesota-based ANI Pharmaceuticals) made by Lupin, the company said in a filing to the stock exchanges. This new medicine helps in lowering blood pressure, relaxes the blood vessels in the brain and can prevent migraine headaches. This drug had an annual sales of $71 million in the US, according to data shared by the Mumbai-based drug maker.

The Mumbai-based drug maker Lupin had a market capitalisation of over ₹64,000 crore as on January 15. It will release the drug (generic Inderal) in four strenghts: 60 milligram (mg), 80 mg, 120 mg, and 160 mg. This is third new launch announced by the company in the last one week. The other two being Varenicline tablets (recommended in the treatment of smoking addictions and dry eye disease), and bromfenac ophthalmic solution (used to treat inflammation and pain among patients who have undergone cataract surgery).

Shares of Lupin have rallied over 84% in the last one year. In the first fortnight of 2024, investors in Lupin have seen their wealth go up by nearly 6%. The company is targetting quarterly sales of $250 million in the next 3-4 years, global chief financial officer Ramesh Swaminathan told CNBC-TV18 in an interview on January 4. In the financial year ending March 2023, the drug maker reported a revenue of $632 million from the US (out of a total revenue of $2 billion).

In the latest second quarter ended September 2023, for the first time in two years, Lupin crossed $200 million in revenue from North America, which made for 38% of the company's total revenue.Aside from the new drug approvals, Lupin shares are also cheering the easing stress on the company's profit margin. Despite being the third largest pharmaceutical company in the US (by prescriptions), increased competition, and rising cost of inputs, had squeezed the profit margin in recent years. However, the growing belief on the street is that the margin squeeze is now over. In the first half of the current financial year ending March 2024, the company clocked an EBITDA margin of 19% compared to just 9% in the same period last year.

Global investment bank Nomura increased the target price on Lupin share to ₹1,593 from ₹1,290 per share earlier citing better earnings potential. Earlier, on December 28, the Mumbai-based broking firm upgraded the rating on Lupin to 'buy' with a new target price of ₹1,440.(Source: Reuters)

Russian President Vladimir Putin Says Russia Is Close to Creating Breakthrough Cancer Vaccines

President Vladimir Putin said that Russian scientists were close to creating vaccines for cancer that could soon be available to patients.

Putin said in televised comments that “we have come very close to the creation of so-called cancer vaccines and immunomodulatory drugs of a new generation”. “I hope that soon they will be effectively used as methods of individual therapy,” he added, speaking at a Moscow forum on future technologies.

Putin did not specify which types of cancer the proposed vaccines would target, nor how. A number of countries and companies are working on cancer vaccines. Last year the UK government signed an agreement with Germany-based BioNTech to launch clinical trials providing “personalised cancer treatments”, aiming to reach 10,000 patients by 2030. Pharmaceutical companies Moderna and Merck & Co are developing an experimental cancer vaccine that a mid-stage study showed cut the chance of recurrence or death from melanoma – the most deadly skin cancer – by half after three years of treatment.

There are currently six licensed vaccines against human papillomaviruses (HPV) that cause many cancers, including cervical cancer, according to the World Health Organization, as well as vaccines against hepatitis B (HBV), which can lead to liver cancer. During the coronavirus pandemic, Russia developed its own Sputnik V vaccine against COVID-19 and sold it to a number of countries, although domestically it ran up against widespread public reluctance to get vaccinated. Putin himself said he had taken Sputnik, in a bid to assure people of its efficacy and safety. (Source: News 18)

Wegovy, the 'Viagra' of Weight-Loss Drugs Flying Off The Shelves

"So this is Wegovy, you take it four times a month," says the 45-year-old. "Before, I thought, 'maybe I'm not getting to be 60, maybe I'm not seeing my grandkids'. But now I'm looking at the future way brighter. I started on 159kg Right now, I'm weighing 93.5kg, so I'm in a really good place." Fuelled by a social media buzz and celebrity users including Elon Musk, Wegovy is a weight-loss drug that has been flying off pharmacy shelves.Such has been the rise in its global sales that its manufacturer, Danish drugmaker Novo Nordisk, last year became Europe's most valuable listed company. "I think the only drug which it can be compared with is Viagra," says Kurt Jacobsen, a professor of business history at Copenhagen Business School, in reference to Wegovy's popularity. Wegovy's manufacturer, Novo Nordisk, cannot make the drug fast enough. Aimed at people who are severely overweight, Wegovy's active ingredient is a medicine called semaglutide, which helps control blood sugar, lowers appetite, and makes patients feel fuller. It is also the active ingredient in sister drug Ozempic, which is used to treat type 2 diabetes. Research suggests that Wegovy patients can lose more than 10% of their body weight. However, there can be side effects for some users, such as nausea and vomiting, and research shows that patients often put weight back on after stopping treatment. These issues have not slowed sales of Wegovy, which increased five-fold in 2023. It is currently available in eight countries - Denmark, Germany, Iceland, Norway, Switzerland, the UAE, the US and the UK - with Japan due to follow at the end of February. In the UK it is now prescribed by some specialist NHS weight-loss management services, for patients who meet specific criteria. It is also available from some private clinics.

Yet as the BBC reported back in September, only limited supplies had come into the country. Meanwhile, Ozempic is now the world's biggest-selling diabetes drug. The runaway sales of both drugs has led to surging earnings at Novo Nordisk. At the end of January it announced that its annual net profit had jumped by 51% to 83bn Danish kroner ($12bn; £9.6bn). Speaking to the BBC, the firm's chief financial officer Karsten Munk Knudsen admits that Ozempic and Wegovy's huge popularity had initially caught the firm off guard. "The demand in the market, both in diabetes and obesity, has just stepped up, much more than we ever forecasted. Much more than anyone forecasted," he says. He expects those strong sales will continue in 2024, "we're guiding for 18 to 26% growth". Whether Novo Nordisk can keep keep up with orders for Wegovy remains to be seen, says Emily Field, a pharmaceutical sector analyst at Barclays bank.

The underlying demand is so overwhelming, they can't make enough of it," she says. Mr Knudsen acknowledges that the company won't be able to meet demand "any time soon", but adds that it is investing heavily to expand manufacturing capacity. "We're really building new facilities like never before." For Denmark, a small country of less than six million people, Novo Nordisk is now so big that it's having an outsized impact on the Danish economy. Denmark's economic growth was 1.1% over the first nine months of 2023. But strip away the pharmaceutical sector, dominated by Novo, and the economy shrank by 0.8%. The country is now publishing separate economic statistics, minus the drugs industry. Casper Nielsen credits Wegovy for this significant weight loss. For almost a century, Novo Nordisk had focused on producing insulin. However the company has been transformed by its discovery of semaglutide in 2004. Several years later the medicine was developed as a treatment for diabetes, and the weight loss effect came as a surprise. Ozempic was approved for sale in the US in 2017, and in 2018 in the EU. Wegovy followed in the US in 2021, and in the EU in 2022. Dr Maria Kruger, a GP and spokesperson for the Danish Society for General Medicine.

Meanwhile, some medical insurance providers in Denmark and the US are refusing to cover Wegovy due to concerns over its high price, together with rising patient numbers, and uncertainly over the length of treatment time. Yet with worldwide obesity levels having almost tripled over the past 50 years, and tipped to hit one billion people by 2030, the success of Wegovy has set off a weight-loss drugs arms race. Back in November, American pharmaceutical firm Eli Lilly was given clearance in the US to sell its rival Zepbound. Its sister drug aimed at treating diabetes, Mounjaro, was already on the market. "Novo and Lilly have such a large head start," says Barclay's Ms Field. "Everyone's tripping hand over foot to catch up." Novo Nordisk's Mr Knudsen shrugged off the increased competition: "The market potential is so big that there's more than enough space for two or even more competitors." Back at Casper Nielsen's home in Zealand, he says that continuing to take Wegovy is keeping the weight off. "Before I'd tried all the different kinds of diets a million times... and it was always the same, same story, I lost a lot of weight. And as soon as I let go of the diet just a little bit, I gained the weight in no time, and even a little bit more. "But now I'm thinking, 'well, I'm gonna actually have my grandkids and I'm going to play with them'. I'm going to do all the things that a granddad should do. The company is in talks with other countries and governments to utilize those facilities in the event of future outbreaks, he said, but did not provide further details on the discussions. Poonawalla said Serum has capacity to manufacture 100 million doses of its malaria vaccine, and could scale up further depending on demand. It has already produced 25 million doses ahead of a launch in the coming months.

The ancient mosquito-borne disease still kills more than half a million people, mainly young children in sub-Saharan Africa, every year. Poonawalla said Serum would focus on exporting its vaccines, such as the malaria shot, to other countries, rather than sign technology transfer deals. Serum is also testing a single-dose vaccine for dengue, another mosquito-borne, painful and sometimes fatal disease, which it developed building on research done by the U.S. National Institutes of Health. That vaccine is in early- to mid-stage trials in India and the company expects to complete late-stage trials in the next three years, the CEO said. Japan's Takeda Pharmaceutical also makes a dengue shot, which is available in countries like Indonesia and Thailand, as well as Argentina and Brazil, which is currently dealing with a major outbreak and not enough vaccine. Other companies such as Indian Immunologicals are also developing vaccines against the disease. (Source: Reuter)

India To Become A Global PowerhoUse In Medical Device And Pharma Exports

India has moved on to become a major exporter of bulk drugs and medical devices, Union Health Minister, Mansukh Mandaviya said last week. According to him, India worked on schemes and plans to de-risk its supply chain from global vagaries and dependence on a single country in terms of obtaining APIs for bulk medicine making.

Previous governments should have provided protection to the local pharma industry against the dumping of medicines by global majors and also control of APIs; but this was not the case, he said. "Today India is self-sustainable in critical API (active pharmaceutical ingredients) making, and our medical exports are expected to reach ₹75,000 crore in the coming days," he said during the inauguration of 39 Greenfield projects under the PLI scheme for bulk drugs and medical devices.

The country has 12,000-odd pharma companies, and bulk drugs continue to be the key requirement for the sector. India continues to import around 70 per cent of medical devices. And the PLI scheme – under which 39 medical device-making plants are being inaugurated or are currently under commissioning – is expected to further bring down the import bill.

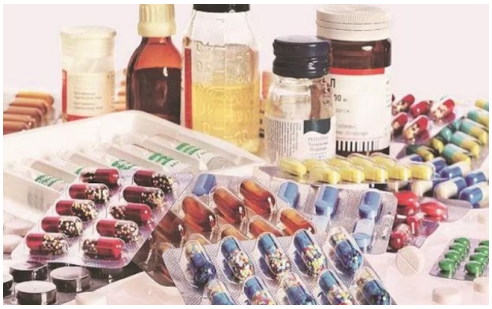
"It is noteworthy that today India has not only reduced its dependence on medicines, API and medical devices, the country is also emerging as a major exporter of these products, thanks to the success of the PLI scheme," he said adding that soon Penicillin G will be made in India. Penicillin production in India stopped some three decades back.

Production Linked Incentive Schemes in India (PLI Scheme)

Some 27 Greenfield Bulk Drug Park projects and 13 Greenfield Manufacturing Plants for Medical Devices under the PLI Scheme were inaugurated. The PLI scheme envisages manufacturing of 41 Bulk Drugs with a total outlay of ₹6,940 crore during the tenure of the scheme from 2020-21 to 2029-30. Some 26 applicants for manufacturing of medical devices have been approved for 138 products under the PLI scheme with total financial outlay of ₹3,420 crore between 2020-21 and 2027-28.

According to Mandaviya, PLI 1.0 with a financial outlay of ₹54,000 crore saw a "good response from the industry" and this led to the introduction of PLI 2.0 at a financial outlay of another ₹15,000 crore. The PLI 2.0 will further consolidate India's position as an exporter. The PLI scheme is a result of wide-ranging deliberations on India's dependence on critical resources, risk to supply chain bottlenecks. "(The) PLI schemes are a success story for us," he said adding that the focus would continue to be on "long-term policies" that aid investment by the industry. (Source: Business Line)

Sun Pharma Recalls 55,000 Bottles Of Generic Drugs From The US Market Due To Manufacturing Norms Violation



Drug major Sun Pharma is recalling around 55,000 bottles of a generic medication to treat gout from the American market due to manufacturing practices norms deviations, according to the US health regulator. The New Jersey-based unit of the Mumbai-based drug major is recalling Febuxostat Tablets in 40 mg and 80 mg strengths, US Food and Drug Administration (USFDA) said in its latest Enforcement Report. Sun Pharmaceutical Industries Inc is recalling 47,520 bottles (40mg) and 7,488 bottles (80 mg) respectively of the medication due to Current Good Manufacturing Practice regulations (CGMP) deviations, it stated.

"Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment," the USFDA stated. The affected lot was produced at Sun Pharma's Dadra-based plant for Memphis-based Northstar Rx LLC, the US regulator noted. As per the USFDA, the company has initiated the Class II nationwide (US) recall on March 4 this year.

As per the USFDA, a class II recall is initiated in a situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. Sun Pharma is one of the leading generic pharmaceutical companies in the US. The US generic drug market was estimated to be around USD 115.2 billion in 2019. It is the largest market for pharmaceutical products. (Source: Business Line)