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NEWS LETTER
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U.S. Supreme Court Rebuffs Novartis, Allows Generic Versions of MS Drug

WASHINGTON: The U.S. Supreme Court on Thursday turned down Novartis' (NOVN.S) bid to block the launch of generic versions of the company's blockbuster multiple sclerosis drug Gilenya in a dispute with China's HEC Pharm Co Ltd (1558.HK) and other generic drugmakers.Novartis had asked the justices to suspend a lower court's ruling that lifted a ban on generic versions of Gilenya, the Switzerland-based company's third highest-selling drug last year with $2.8 billion in sales.

Novartis sued HEC and more than a dozen other generic drug makers, accusing them of patent infringement, in Delaware federal court after they applied for U.S. Food and Drug Administration (FDA) approval of Gilenya generics.

Novartis settled with some of the drugmakers it had sued, allowing for some Gilenya generics before a key patent's 2027 expiration. Companies that settled with Novartis included India-based Aurobindo Pharma Ltd (ARBN.NS), Dr. Reddy's Laboratories (REDY.NS) and Sun Pharmaceutical Industries Ltd (SUN.NS), Pennsylvania-based Viatris Inc's (VTRS.O) Mylan Pharmaceuticals and privately held Canada-based Apotex Inc. The FDA in 2010 approved Gilenya, a once-daily pill used to treat relapsing forms of multiple sclerosis, a chronic disease that affects the central nervous system. Novartis said in September that it expects to lose $300 million in sales for the rest of 2022 if the Gilenya generics are launched.

The patent-focused U.S. Court of Appeals for the Federal Circuit ruled in June that a key Novartis patent for Gilenya was invalid. U.S. Chief Justice John Roberts, granting a request by Novartis on Sept. 29, temporarily prevented the Federal Circuit from issuing a mandate as planned on Oct. 4 to lift a federal judge's injunction that blocked generic versions of Gilenya based on the Novartis patent claims.

Roberts acted after Novartis said that green-lighting the generics would hurt the company in "ways that could be impossible to calculate at an after-the-fact damages trial" and that it was likely to win a Supreme Court appeal of the underlying case. HEC told the Supreme Court that Novartis makes $3.8 million per day from Gilenya sales in the United States alone. "If Novartis does not prevail in this Court, it will improperly extract $3.8 million from payors and patients every day its requested stay remains in effect," HEC said. "And not one penny of those improper monopoly revenues will be recoverable from Novartis by anyone." A spokesperson for Novartis said the company will "continue to vigorously defend the validity of the Gilenya patent" and plans to petition the high court to review the Federal Circuit's decision. (Source Reuters)

In Africa's Monkeypox Outbreak, Sickness And Death Go Undetected

At a village clinic in central Congo, separated from the world by a tangle of waterways and forests, six-year-old Angelika Lifafu grips her dress and screams as nurses in protective suits pick at one of hundreds of boils that trouble her delicate skin.

Her uncle, 12-year-old Lisungi Lifafu, sits at the foot of her bed, facing away from the sunlight that pours through the doorway and pains his swollen, weeping eyes. When nurses approach, he raises his chin, but cannot look up.

The children have monkeypox, a disease first detected in Congo 50 years ago, but cases of which have spiked in West and Central Africa since 2019. The illness received little attention until it spread worldwide this year, infecting 77,000 people.
Global health bodies have counted far fewer cases in Africa during the current outbreak than in Europe and the United States, which snapped up the limited number of vaccines this year when the illness arrived at their shores.

But the outbreak, and death toll, in Congo could be much greater than recorded in official statistics, Reuters reporting shows, in large part because testing in underequipped, rural areas is so limited and effective medicines are unavailable.

During a six-day trip to the remote region of Tshopo this month, Reuters reporters found about 20 monkeypox patients, including two who had died, whose cases were not recorded until reporters visited. None of them, including Angelika and Lisungi, had access to vaccines or anti-viral drugs. (Source: Reuters)

Hyderabad Pharma City is In The Final Leg Of Planning, To Be Launched Soon

The Hyderabad Pharma City (HPC), a mega pharma park developed by the Telangana Government, is likely to be launched soon. It is expected to attract investment worth USD 9.7 billion and generate employment for 560,000 people. HPC is the world's largest integrated cluster in Hyderabad for pharmaceutical industries, thrusting on R&D and manufacturing. The cluster has been recognized as the National Investment and Manufacturing Zone (NIMZ) by the Government of India, Center of Excellence.

"The project, coming up at about 25 km from Shamshabad airport, is in its final leg of planning and we hope to launch it soon,'' Shakti M Nagappan, Director, Life Sciences, Government of Telangana and CEO, HPC told BusinessLine. According to the Government data, the Life Sciences sector in Telangana attracted ₹6,400 crore investment from 215 companies in 2021-22 which was 200 per cent more than the investment attracted by the industry at ₹2,766 crore from about 150 companies in FY21.

Hyderabad Pharma City is one of our flagship initiatives, having the potential to save and improve millions of lives worldwide by supporting the development and manufacturing of life-saving, quality and affordable medicines, he said. The Genome Valley in Hyderabad has attracted a unique blend of companies across the value chain of the life sciences and has the largest multi-tenanted labspace in the country and one of the highest in the region – housing more than 3 million sqft at international standards.

Hyderabad's extraordinary talent pool, infrastructure, including multi-tenanted laboratory space, incubation facilities, utility infrastructure, testing facilities and other necessary ingredients required to discover, develop and manufacture are making the city as a "highly attractive destination,'' for global life sciences companies, Nagappan said adding that the "progressive'' Government policies were also a positive factor.

"This highlights the growing role and impact of Hyderabad's life sciences ecosystem and the State's endeavour to ensure required support to the sector,'' Nagappan said. (Source: Business Line)

Indian Pharma Centre Initiates Probe After WHO Red Flags Four Products From Indian Drugmaker

The Health Ministry has launched an investigation, after a medical product alert was issued by the World Health Organization on four contaminated medicines from an Indian drugmaker, "potentially linked" to acute kidney injuries and 66 deaths among children in Gambia. The four medicines are cough and cold syrups produced by Maiden Pharmaceuticals Limited. The products were reported to have been contaminated with diethylene glycol or ethylene glycol. While investigations are underway, at the WHO and Indian regulatory levels, experts worry at the impact this could have on the Indian pharmaceutical industry.

The Central Drugs Standard Control Organisation (CDSCO) had commenced its probe after the WHO first alerted them on September 29. The regulator has since been in touch with Haryana's State Regualtory Authority, where the company's manufacturing unit is located. An official from the Health Ministry pointed out that an importing country usually tests products on quality parameters, and satisfies itself before their release for use in the country. The WHO has been requested to share with the CDSCO the report on establishment of causal relation to death with the medical products in question, photographs of labels/ products etc. That report is awaited.

The note clarified that the product has been exported only to Gambia and the company did not have permission to sell in India. Controlled samples of the same batch of the four products have been sent to the Regional Drug Testing lab, Chandigarh, and its results would guide future action, it added.

Concerned that these 'substandard' products could impact the brand image of Indian pharmaceutical exports, the Pharmaceutical Export Promotion Council (Pharmexcil) — an arm of the Commerce Ministry — has also sought information from the company on the development. "This is a dent on the brand image of Indian pharma exports as the alert could also make other countries take a relook at certain products being exported from India. We have asked the company to provide information and investigate the reasons of serious adverse events (SAE) and provide information to us," R Uday Bhaskar, Director-General, Pharmexcil, told businessline. Maiden Pharma has been registered with Pharmexcil since 2006 as a small scale manufacturer. Meanwhile, Naresh Kumar Goyal, a Maiden director, told Reuters it heard about the deaths only on Thursday morning and were trying to find out details. "We are trying to find out with the buyer and all that what has happened exactly. We are not selling anything in India." (Source: Business Line)

Canada, Japan And Europe Import Iranian Pharmaceuticals

TEHRAN – Iranian-made pharmaceuticals are currently exported to Canada, Japan, and Europe, Faramarz Ekhteraei, chairman of the Iranian Pharmaceutical Industries Syndicate, has said. Emphasizing that 72 percent of the country's pharmaceutical raw materials are domestically produced, he added that Iran has many capabilities in the pharmaceutical industry and investors should pay attention to it. Pharmaceuticals should be taken into consideration due to their strategic importance in the treatment and health sector because there are capacities in the world for the production of effective medicinal substances that we can produce with the help of knowledge-based companies and pharmaceutical manufacturers with quality and low prices, he highlighted.

According to him, the technical speed of the pharmaceutical industry is high and it should be considered for investment. We have achieved acceptable growth in the fields of packaging, active ingredients, and the pharmaceutical chain, and the government should also provide more support in this field. Iran's API and Pharmaceutical Packaging Syndicate and Iran Food and Drug Administration (IFDA) will organize the 4th Pharmex International Exhibition (Middle East) from August 23 to 26, at Iran Mall International Expo Center. On the sidelines of the event, a "special meeting for the development of commercial cooperation in the pharmaceutical industry" will also be held for the first time in the country.

Rise in pharmaceuticals, medical production The import of pharmaceuticals has declined in Iran by 91 percent, which shows the capability of the country's pharmaceutical industry, Mohammad Reza Shanehsaz, former head of the Food and Drug Administration, said last October. Today, all medicine used in the treatment of coronavirus are produced by domestic manufacturers, and if we wanted to import all the items, there would be a high exchange rate, he further stated, emphasizing that COVID-19 vaccine development indicates the pharmaceutical industry's capability.

In 2018, 67 percent of the active pharmaceutical ingredients (APIs) used to produce drugs in Iran were made locally. A total of 227 knowledge-based firms are supplying medical equipment for health centers across the country, according to the Vice Presidency for Science and Technology.

Knowledge-based companies can produce any medicine effective in countering coronavirus or approved by the scientific committee within a week to 10 days, Sourena Sattari, vice president for science and technology, said. Also, Iran is capable of producing 28 types of biopharmaceuticals, placing the country third in Asia. Based on innovative indicators of health technology development in 2021, Iran was ranked 60th among 132 countries, which shows an improvement of 60 steps compared to 2014, the deputy health minister for research and technology, has announced. Despite the sanctions that have existed since the beginning of the Islamic Revolution, Iran has the strongest health system in the region. (Source: Tehran Times)

Centre Probes 4 Cough Syrups After WHO Alert On 66 Child Deaths In Gambia

WHO chief Tedros Adhanom Ghebreyesus have said the four syrups "have been potentially linked with acute kidney injuries and 66 deaths among children". New Delhi: The government has started an investigation into four cough syrups manufactured by a Haryana-based pharmaceutical firm after the World Health Organization (WHO) warned that they could be linked to the deaths of 66 children in The Gambia.

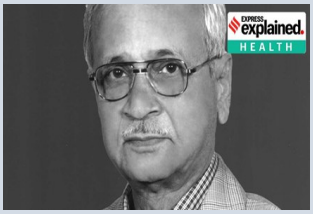
Top sources in the Ministry of Health and Family Welfare said the WHO alerted Drugs Controller General of India (DCGI) about the cough syrups. The Central Drugs Standard Control Organisation immediately took up the matter with the Haryana regulatory authority and launched a detailed investigation, the sources said. The cough syrups have been manufactured by M/s Maiden Pharmaceutical Limited in Haryana's Sonepat, the sources said. They added that as per the information available at this point, it seems the firm had exported these products only to The Gambia. The company is yet to respond to the allegations. The WHO has warned that the syrups may have been distributed outside the West African country and a global exposure is "possible".

WHO chief Tedros Adhanom Ghebreyesus told reporters yesterday that the four cold and cough syrups "have been potentially linked with acute kidney injuries and 66 deaths among children". According to the WHO alert, the four products are Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup and Magrip N Cold Syrup.

"To date, the stated manufacturer has not provided guarantees to WHO on the safety and quality of these products," the alert said, adding that laboratory analysis of samples of the products "confirms that they contain unacceptable amounts of diethylene glycol and ethylene glycol as contaminants." Those substances are toxic to humans and can be fatal, it said, adding that the toxic effect "can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death."

Sources from the ministry said the "exact one to one causal relation of death" has not yet been provided by WHO". They added that the WHO is yet to share the details and photos of labels confirming the manufacturer of the products.The WHO has not yet provided details on when these deaths took place. (Source: NDTV)

Dr Dilip Mahalanabis Passes Away: How He Came Up With ORS, Which Revolutionised Diarrhoea Treatment



Dr Dilip Mahalanabis was working in overflowing refugee camps during the 1971 Bangladesh Liberation war when he came up with ORS, which The Lancet called "the most important medical discovery of the 20th century.''Dr Dilip Mahalanabis, 87, passed away at a Kolkata hospital on October 16. While Oral Rehydration Solution (ORS) as a simple, effective remedy for dehydration is known around the world, the physician who pioneered the treatment is less famous. This physician, Dr Dilip Mahalanabis, passed away at a Kolkata hospital on Sunday (October 16). Dr Mahalanabis, 87, was suffering from lung infection and other age-related ailments, the Press Trust of India (PTI) reported.

India-made cough syrups and deaths in Gambia: what we know so far According to the World Health Organisation (WHO), diarrhoeal diseases, such as cholera, are among the leading causes of mortality in infants and young children in many developing countries, where the patient dies of dehydration. ORS, a combination of water, glucose and salts, is a simple and cost-effective method of preventing this. Dr Mahalanabis was working in overflowing refugee camps during the 1971 Bangladesh Liberation war when he came up with ORS, which The Lancet called "the most important medical discovery of the 20th century.'' From 1975 to 1979, Dr Mahalanabis worked in cholera control for WHO in Afghanistan, Egypt and Yemen. During the 1980s, he worked as a WHO consultant on research on the management of bacterial diseases. In 2002, Dr Dilip Mahalanabis along with Dr Nathaniel F Pierce was awarded the Pollin Prize by Columbia University (considered the equivalent of Nobel in peadiatrics). "His death marks the end of an era. Oral rehydration is still the mainstay of treatment for diarrhoeal diseases in children. Before the use of ORT, the only treatment was intravenous fluid infusion, which was neither cost-effective nor easy. Due to Dr Mahalanabis's persistent efforts, ORT was made a household name," said Dr Sampada Tambolkar, professor of paediatrics at Dr D Y Patil medical college, Pune.

We explain the story of the doctor and his discovery that saved millions of lives. Born on November 12, 1934 in West Bengal, Dr Mahalanabis studied in Kolkata and London, and joined the Johns Hopkins University International Centre for Medical Research and Training in Kolkata in the 1960s, where he carried out research in oral rehydration therapy. When the 1971 war broke out, millions of people from then East Pakistan took refuge in India. Clean drinking water and sanitation were problems at these refugee camps, and cholera and diarrhoea broke out among people anyway exhausted and dehydrated. Dr Mahalanabis and his team were working in one such camp at Bongaon. Stocks of intravenous fluids were running out, on top of which there weren't enough trained personnel to administer the IV treatment.

From his research, Dr Mahalanabis knew that a solution of sugar and salt, which would increase water absorption by the body, could save lives. He and his team then prepared solutions of salt and glucose in water and began storing them in large drums, from where patients or their relatives could help themselves. Dr Mahalanabis later wrote in WHO's South-East Asia Journal of Public Health about that period in 1971, "Available resources for the treatment of cholera were mobilised but basic handicaps still existed. The huge amounts of intravenous fluids that would be required, plus the problems of transport and lack of trained personnel for their administration, represented an almost insurmountable logistical problem in treating cholera effectively under such circumstances by the standard methods currently in use. We suggested the use of oral fluids as the only recourse in this situation." To convince people the new treatment would work, they were told it was an oral form of saline. "The oral solution that we elected to use consisted of 22 gm glucose (as commercial monohydrate), 3.5 gm sodium chloride (as table salt) and 2.5 gm sodium bicarbonate (as baking soda) per liter of water. This was the simplest formula, containing the minimum number of ingredients, previously found to be effective in severely ill patients with cholera," Dr Mahalanabis wrote. In another article from the Bulletin of the WHO carried by the USA's National Library of Medicine, Dr Mahalanabis is quoted as saying, "Within two or three weeks, we realised that it [ORS treatment] was working and that it seemed to be all right in the hands of untrained people… We prepared pamphlets describing how to mix salt and glucose and distributed them along the border. The information was also broadcast on a clandestine Bangladeshi radio station."

Soon the fatality rate in Dr Mahalanabis's camp was down to 3 per cent, compared with the 20 and 30 per cent in camps that used only intravenous fluids. Dr Dhiman Barua, head of the Bacterial Diseases Unit of WHO, visited the camp managed by Dr Mahalanabis, and started popularising the ORS method of treatment. While initially, the medical fraternity was septical, the WHO eventually adopted ORS as the standard method for treating cholera and other diarrhoeal diseases. Today, the WHO recommends a combination of sodium chloride, anhydrous glucose, potassium chloride and Trisodium citrate dihydrate as the ORS formula. In India, July 29 is observed as ORS Day.

"One of the advantages with ORS is that even untrained people can administer it and keep the crisis in check till the patient is admitted to the hospital. It contains electrolytes in right proportions and is given to babies and adults suffering from diarrhoea. This low-cost solution for a very common problem was pioneered by Dr Dilip Mahalanabis," Dr. Sameer Desai, Pediatric Orthopaedic Surgeon and consultant at Pune's KEM hospital, said. Using ORS. The Union Health Ministry has popularised guidelines on preparing and using ORS available in powder form at health centres and chemists. The guidelines, available at the India Health Portal site, advise that contents of the ORS packet should be mixed with the correct amount of water in a clean container. This is important, because too little water could make the diarrhoea worse, the government cautions. Also, the ORS must be added only to water, and not to milk, soup, fruit juice, or any soft drink. Sugar should not be added to the solution. After stirring well, the solution should be given to the child from a clean cup, and not a bottle. The National Health Portal gives a step-by-step guide to preparing formulation at home as well. Six level teaspoon full of sugar (1 spoon = 5 g) and half a level spoonful of salt should be mixed with a litre (five 200-ml cups) of clean water), and stirred until the sugar and salt dissolve. "The home-made solution is adequate in most cases and is very effective for rehydration," the National Health Portal says. It cautions: "Be very careful to mix the correct amounts. Too much sugar can make the diarrhoea worse and too much salt can be extremely harmful to the child." The ORS solution should be covered and not kept for more than 24 hours, due to the risk of bacterial contamination, the portal says. (Source: Indian Express)