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NEWS LETTER
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Cancer Research With Homeopathy Reveal Killing Cancer Cells in Lab Model

A research conducted at Tata Memorial's Navi Mumbai based research facility Advanced Centre for Treatment, Research and Education in Cancer (ACTREC) under homeopath Dr Rajesh Shah revealed killing of cancer cells in lab model with three new homeopathy drugs. The study has shown positive effects of high dilution potential medicines which are often criticised for lack of scientific evidence. The research break-through is the first of its kind in over fifty years in the field of homeopathy.

Dr Shah who was felicitated with the National Award by the Union Ayush Ministry last year for another drug-discovery is the brain behind this path-breaking study in the field of homeopathy.Cancer claimed 9.6 million lives in the world in 2018 and India's share was a worrying 8.17 percent, according to statistics from World Health Organizations (WHO) International Agency for research on cancer. The research done at the lab level was successfully conducted for three new drugs including Cancer Nosode which has been developed by Dr Shah, from five types of different cancer tissues. While sharing insights on the research, Dr Shah said, "I have been working on developing new homeopathic drugs for over two decades. Nosode is one of my major areas of interest. Cancer is a major challenge affecting millions of people in India and the numbers have seen a significantly sharp rise in the last few years. I decided to work towards scientifically developing the Cancer Nosode, which could fight cancer cells." He further added, "The development process started many years ago. In my opinion and experience, no single system of medicine has a foolproof protocol to fight cancer. Homeopathy has the potential to support cancer treatment. I believe the initial results are encouraging.

Dr Shah's experiments in the last two decades in laboratory models, animal studies and human trials have shown irrefutable scientific evidence. Interestingly, scientists at IIT-B led by a chemist Dr Jayesh Bellare have shown the nano-particles of the source materials in high-dilution homeopathic medicines, which were earlier believed to be containing some kind of 'energy'. Homeopathy, originally born in Germany, is getting a scientific face-lift and India is a leader in this revolution," added Dr Shah. Dr Raj K Manchanda, former director general of Central Council for Research in Homeopathy (CCRH) under the Union Ayush Ministry said, "Nosodes prepared from germs and diseased tissues are commonly used in homeopathic practice. Dr. Shah has scientifically developed new Nosodes from specific cancer tissues as well as a certain virus using modern techniques. The Cancer Nosode, the HIV Nosode and the Hepatitis C Nosode demonstrate anti-cancer efficacy in cell-line models is strong preliminary evidence towards opening up many new research avenues. Further validation using this Nosode in animal and human models must be explored. I am happy that new homeopathy drug research is done in India and that too by a practicing homeopath. In the past, in a collaborative project of CCRH with Bose institute, Kolkata scientists have shown and published the effect of traditional homeopathic drugs in different cell lines. Even the mechanism of action of these drugs was elucidated. These developments are very important to enrich the scientific basis of homeopathy," he added.

Dr Vedang Murthy, a radiation oncologist and researcher at Tata Memorial Hospital Mumbai observed, "Cancer is a very difficult disease to treat and we are always on the lookout for new approaches in its treatment. Early research in the laboratory with a drug prepared from cancer tissues has shown activity against cancer cells. Dr Shah has shown preliminary results which should be strengthened by further research. These results may indicate some efficacy of homeopathy in the laboratory model. This seems like an early exploration of untapped potential of homeopathy against cancer.

The initial scientific testing and experiments were done at ACTREC. A total of three drugs were prepared from Cancer tissues, HIV Virus, and Hepatitis C Virus. The drugs show effective inhibition of growth in cancer cells. The homeopathic drugs show anti-cancer activity on cell lines related to the liver, cervix, breast, and lung cancers. The anti-cancer activity was measured as percentage growth inhibition. Earlier, HIV Nosode and Hepatitis C Nosode have also shown specific anti-disease and anti-cancer effects in Dr. Shah's preliminary studies in coordination with Dr. A.R. Khuda-Bukhsh, an eminent molecular biologist from Kalyani University, West Bengal. The recent study has strengthened the efficacy of the research. Since HIV and Hepatitis C viruses are potentially cancer-producing substances, Dr. Shah has explored their effects against cancer successfully. The projects were aimed at reviewing the research question of the efficacy of homeopathic medicines against cancer in potential form using the standard laboratory model for cancer research. Research papers have been published in international peer -reviewed journals and presented at prestigious conferences. The scientific monographs have been submitted to the concerned government departments for regulatory evaluation. In the recent past, Dr. Shah has collaborated with about 35 scientists from seven institutions such as Haffkine Institute, ICT, Nair, Tata, Nair Hospital and IIT-B for experiments related to new drug research.

The study has once more created scientific evidence of the effects of homeopathic medicines in a laboratory model as well as supported The Law of Similars (like cures like), the fundamental principle of homeopathy. Nosodes are homeopathic drugs prepared from bacteria, virus, and diseased tissues, using a unique process called 'potentization' which renders the drugs to be safe yet effective. Such Nosodes have been in use in homeopathy for over 180 years. The HIV Nosode was also developed by Dr. Shah through a similar process as per the dictates of Dr. Hahnemann, the founder of Homeopathy. Nosodes are not vaccines but are known to be effective against many diseases. (Source: PharmaBiz.com)

India: Vaccines Drive Pharma Boom in Hyderabad

HYDERABAD, India: With one-third of the world's vaccine demand among children shipped from its doors in Hyderabad, Genome Valley has now emerged as India's top life sciences cluster, beating Bengaluru and Chennai to the game. Touted by many as Asia's equivalent to the Boston Life Sciences Corridor – the US cluster is the largest globally – Genome Valley is located roughly 60 km north -east of the city's thriving information technology hub, and houses about 200 major firms that employ more than 10,000 scientists

Driving this massive supply are pharma majors such as Bharat Biotech, Shantha Biotechnics, Indian Immunologicals Limited and Biological E, among others. Some of the vaccines supplied are: Tetanus -Diphtheria (combination), Pentavalent, Japanese Encephalitis, Rotavirus, Typhoid Conjugate and Hepatitis B&C.

"Collectively, India contributes 70% of the world's vaccine requirement. Apart from Genome Valley, the rest is supplied by Serum Institute of India, Pune," said a scientist from Genome Valley. It's limited workforce – in comparison to other clusters in India – is because Genome Valley is a "new cluster that has been "systematically planned to develop new-age solutions to bio tech products" and is not clubbed with pharmaceutical and bulk drug industries, as is the case in other places," he added.

While the last three years alone have seen Genome Valley draw investments of Rs 6,000 to Rs 6,500 crore, there's more in the pipeline, said Shakthi M Nagappan, director, life sciences & pharma, of Telangana government. "We have also created a company, Life Sciences Infrastructure Ltd, to raise equity funds worth Rs 1,000 crore to support the growth of pharma and life sciences in Hyderabad. This is the first of its kind fund in India. Our aim is to create assets worth Rs 3,000 to Rs 3,500 crore in the city," he said.

With a string of top-end brands from Switzerland, Canada and even India like Ferring Pharmaceuticals, Syngene International, Jamb Pharmaceuticals among others making their way into the cluster, authorities are confident of realising this goal soon.

Genome Valley has added value to Hyderabad," said Dr K R Kumar, managing director of the Madrid-based drug major, Chemo Formulations, the first Spanish drug company to set foot in India. It's base in Hyderabad is the only other finished product research and development centre, outside of Spain. In our phase 2 development at Genome Valley, expected to be up and running by 2020, we will go commercial and are expecting to manufacture 500 million tablets every year. Also, after the success of oral R&D, we are now planning to bring injectable R&D to Hyderabad, which is only available in Spain now," Kumar said.

Biological E recently launched the measles rubella vaccine – only the second in the world to develop the product. While it has four facilities at Genome Valley, it is eyeing a further scale-up. The company's COO, N Laxminarayana attributed the growth to two reasons, a high-quality ecosystem that supports R&D in biotechnology and a talent pool.

"The high-quality innovation here has led to a reverse brain drain," he says. "Unlike earlier, expats are more than willing to return to India," In his eight-member team of senior executives, three are expats. (Source: Economic Times)

Seven of Top 10 Drug Brands Sold in India are From Multinational Companies

Home-grown drug firms have 80 per cent of the Rs 1.36 trillion domestic pharmaceuticals market but when it comes to the top selling medicine brands in India, multinational companies (MNCs) rule.

Of the top 10 drug brands by sales, seven belong to MNCs. The top selling ones is of Danish drug major Novo Nordisk — an insulin medicine called Mixtard that had sales of Rs 539 crore in September on an MAT (moving annual turnover or past 12 months' sales) basis. Though a mature brand, its sales growth rate was 8.4 per cent in September, shows data from market researcher AIOCD AWACS.

The second-largest selling brand is also a diabetics medicine, Lantus, sold by French drugmaker Sanofi. Lantus is one of the top selling brands that Sanofi has globally, annual sale in 2018 being €3,565 million (close to $4 billion). The brand, however, faces stiff competition in the American and European Union markets and global sale declined 19 per cent in the 2018 calendar year.

In India, though, Lantus seems to be doing well, with 18.4 per cent growth in MAT value, as of September. Also, the brand has managed to scale up its rank over recent years here, despite Sanofi introducing a new insulin brand, Toujeo, in 2015. In March 2017, Lantus was the fourth largest selling brand in India.

Says an analyst who tracks MNCs: "The multinationals follow a unique marketing approach. They maintain a close monitor on first-time insulin patients and ensure physicians prescribe their brand. Insulin is a prescription brand, and no one changes it until the doctor asks them to. This helps the companies to have stickiness for their brands."

The third-largest brand by sales is also a diabetes medicine. This is Glycomet GP from Indian drugmaker USV, which clocked sales of Rs 483 crore (MAT, September), on the heels of Lantus (Rs 499 crore). In fact, the top five largest selling brands are all medicines for diabetes. Not a surprise, with this country being home to 72 million diabetics.

British drug major GlaxoSmithKline Pharma's anti-infective drug, Augmentin, is sixth in the list. The broad spectrum antibiotic had growth of 18.2 per cent by sales and contributes to a tenth of the company's turnover here.

Himalaya Drug Company's popular Liv 52 (launched in the 1950s) to treat liver disorder has been among the top selling drugs in India over the years. It, however, clocked a low single digit growth rate (4.7 per cent), inching towards annual turnover of Rs 400 crore.

Chronic therapies are the largest selling brands, as patients use these regularly. The top 10 corporates contribute to 43 per cent of the domestic pharma market. (Source: Business Standard)

Indian Govt to Come Up With List of Over-the-Counter Drugs Soon

NEW DELHI: The government is set to come up with a list of over-the-counter (OTC) medicines under a separate schedule by making changes in the drug law with stringent regulations on quality, advertisement and pricing of such products.

"The move is aimed at promoting self-care and reducing the cost of treatment without compromising patient safety. It will also help us ensure that 'prescription-only' drugs are not misused, while other commonly used medicines which are not toxic are easily available to patients," a senior official told TOI.

The decision to have separate provision for OTC under the Drugs and Cosmetics Act was taken in a meeting of the Drugs Consultative Committee (DCC) under the health ministry last month. DCC's decision is based on recommendations of a sub-committee formed earlier to examine the issue. The sub-committee is of the opinion that there is an urgent need for defining OTC drugs and to lay down specific provisions for the regulation of OTC drugs in the country," the DCC noted in its minutes of the meeting.

The DCC has directed the sub-committee to identify such list of OTC products along with conditions and frame draft for amendments in the law. At present, there is no definition of OTC medicines and therefore, any medicine that is not a 'prescription-only' product, automatically qualifies as OTC. Pharmacists are free to sell such products on their own and patients can buy them without any medical advice or consultation.

Commonly used analgesics like paracetamol and ibuprofen and medicines for cough, cold and flu fall under the OTC category.
Apart from the advertisement norms and definition, the proposed changes will include basic characteristics of OTC drugs and their classification into OTC-1 and OTC-2 based on safety, therapeutic index, need for accessibility to patients, availability, non-habit forming nature, supply chain mechanism and socio-economic conditions of the country.

It will also define criteria and conditions for any medicine to switch from prescription drugs to OTC category as well as regulation for new OTC drug approval, distribution & sale. Such OTC products can also be advertised, whereas advertisement of prescription drugs is prohibited under the law. In the absence of a clear definition and legal recognition to OTC products, it is difficult to regulate them. On one hand, these are pharmaceutical products or medicines and hence fall under the drug law. However, since many of them are not listed under Schedule H and X – which are for 'prescription-only' products – they circumvent the regulation," an official said.

Companies often also tweak commonly used formulations to bring their popular products out of the prescription-only list and then sell such products as OTC under similar sounding brands. This also helps them circumvent price control at times as the changed combination is unlikely to be part of the price controlled National List of Essential Medicines (NLEM).

Similarly, newly launched products are often not part of the Schedule H and X, and companies or chemists are free to sell them as OTC without prescription till the time they are brought under the provisions of the law.

The government and the regulator are also concerned about chemists pushing some high-end antibiotics as OTC products, causing potential risk of antimicrobial resistance. (Source: The Economic Times)

Mammograms the 'Best' Form of Screening Breast Cancer for India

Despite controversies—and several studies—in the West over the efficacy of screening for breast cancer via mammograms, especially in younger women, for India, mammograms remain the "best" form of screening method. The argument against mammograms for screening breast cancer in younger women is that because of the denser breast tissue, it is difficult to differentiate between healthy tissue and the malignant one because of the similarity in the way they both are present on the picture created by a mammogram.

However, doctors in India are dealing with the issue by using a "digital mammogram", combining it with ultrasound and MRI in high risk cases, Dr Harit Chaturvedi, chairman, Max Institute of Cancer Care, told THE WEEK. Chaturvedi also said a section of studies have also indicated that screening reduced mortality levels among women with breast cancer by 40 per cent, although there were several other factors that needed to be considered to determine the exact cause that brought the death rate down among those women.

While in the West, breast cancer was being seen in the later years (50-60 years), in India, the incidence was higher among women between 40-50 years of age, he said. According to recent WHO data, breast cancer impacted over 2.1 million women each year, and also leads to the highest number of cancer-related deaths among women, he added. In India, incidence of breast cancer is the highest among cancers in women, and each year, about 1.6 lakh new cases are being reported in the country.

"There are various factors that might increase the risk of breast cancer in women such as obesity, late or no children, lack of breast-feeding, alcohol, and smoking," he said. Women need to be wary of the key symptoms of the disease such as lump in the breast, nipple discharge, skin changes over breast, pain in the breast and pay attention to their lifestyle, too, said Chaturvedi.
"Among the current image modalities, we have digital mammography, which is better than conventional mammography. The mammography machine that we have uses the advanced technique of tomosynthesis, which is basically like a CT scan where thinner sections of the breast are analysed. Besides, we also use ultrasound and MRI in case of high-risk cases," said Dr Bharat Aggarwal, director, radiology services, Max Super Specialty Hospital, Saket.

Owing to a "scarcity" of radiologists and limited expertise in breast cancer diagnostics across Asia, Max Healthcare is partnering with Fujifilm to train doctors in early detection of cancer. Spokespersons from Fujifilm recently announced that the company would be sponsoring an advanced fellowship in breast imaging with Max Healthcare, under the "guidance" of Chaturvedi and Aggarwal. Doctors would be trained in breast mammography, breast MR, and breast ultrasound techniques for six months through the Max-Fujifilm collaboration fellowship. Each year, the programme will train two select radiologists in early detection of breast cancer.

While screening was important, the country also needs to have trained radiologists to read the images accurately, said Chander Shekhar Sibal, executive vice president and head of medical division at Fujifilm India. (Source: The Week)

USFDA Impact: Ranitidine Under Lens After Carcinogen Alert

New Delhi: Indian authorities are closely monitoring the sale of heartburn drug Ranitidine after the US drug regulator said it had found a cancer-causing impurity called N-nitrosodimethylanine (NDMA) in some products containing Ranitidine.

Ranitidine is a commonly prescribed medicine for countering acidity and is on the World Health Organisation's 'Model List of Essential Medicines'. In India, a host of companies including GalxoSmithKline, JB Chemicals, Cadila Pharma, Zydus Cadila, Dr Reddy's, Sun Pharmaceuticals sell over 180 versions of the drug. The market size for Ranitidine brand in India is Rs 688.6 crore, as per data shared by AIOCD PharmaTrac.

To ensure patient safety, the Drug Controller General of India (DCGI) directed state drug regulators to ask pharmaceutical companies to check their products for the carcinogen. It also asked them to ensure that the drug is sold only under prescription.

"The drug Ranitidine is approved for multiple indications in the country and is available in various formulations including tablets, injections, etc. It is a prescription drug included in Schedule H and, therefore, it should be sold by retail only under prescription of a registered medical practitioner," the DCGI's letter said. ET has seen a copy of the letter. Last week the US and European Union regulators said they were investigating the discovery of NDMA in branded and generic Zantac. "Subject experts have also been reviewing the situation and an advisory may follow in the days to come, but as of now there is nothing to panic," said a senior official in the drug regulatory authority, requesting not to be named.

Experts vouch for the benefits of the medicine. "Ranitidine is one of the oldest drugs to be used in acidity and upper intestinal ulcers, and has been considered to be safer than similar other drugs like proton pump blockers (eg. Pantoprazole), said Anoop Misra. Chairman, Fortis-C-DOC Centre of Excellence for Diabetes, Metabolic Diseases and Endocrinology. We are using it frequently, especially in patients with renal dysfunction."

According to a GSK spokesperson, the company has been contacted by India's drug regulatory authorities regarding the detection of NDMA in Ranitidine products and the queries have been responded to. "GSK is continuing investigations into the potential source of the NDMA. These investigations include continued engagement with GSK's API suppliers, including Dr. Reddy's and Saraca Laboratories Limited. GSK has engaged external laboratories to conduct tests on the API and on the finished product batches of Zantac IV (injection). Initial results are expected by the end of September 2019. The testing is being extended to include batches of tablets and potentially other dose forms. Market-specific test results will be available later," the spokesperson said.

A spokesperson for Sanofi said the company does not sell the product in India. "Ranitidine prescription products have been authorised on the market for over 35 years and in a number of markets an OTC version of ranitidine has been available to consumers for over two decades. The range of products meet all specified quality and safety requirements for use," the person said. (Source: Economic Times)

China Drugmaker Blasts Controversial Campaign to Slash Pharma Prices

China's aggressive campaign to bring down drug prices is leading to a "vicious cycle" and will prevent the emergence of a national pharmaceutical champion, said one of the country's biggest drug makers. In some of the strongest criticism yet over a new policy that is likely to save China tens of billions of dollars, but has roiled healthcare stocks and led to widespread company profit warnings, Stephen Tse, vice president of Sino Biopharmaceutical, said that the program will undermine local firms' ability to invest and grow.

"If prices are kept low, you won't see the rise of any big pharmas on the horizon," said Tse, who is also spokesperson for China's third-largest drugmaker by market value. "It won't work if you don't have a high enough gross margin to support your research and development investment." The controversial policy has already caused the prices of 25 commonly used drugs — ranging from cholesterol treatments to chemotherapy — to drop more than 60% nationwide, and will expand. While the plan is to re-direct the cost savings towards covering top-of-the-line drugs and treatments, the program is rapidly eroding company profits, potentially hampering China's goal of nurturing globally competitive companies in the scientific field.

Under the system, drugmakers compete for tenders to supply generic drugs to public hospitals nationwide, under-cutting one another to secure supply contracts. Although China has softened the terms of the exercise to allow for three suppliers and not just one, both local and foreign drug manufacturers are feeling the pressure.

Sino Biopharma chose not to continue to bid down the price of its own drugs in the program after the first round, said Tse. In the first round of bidding last December, it dropped prices for its hepatitis B treatment entecavir by more than 90%, only to be undercut by peers in the second round which took place last month. It could have gone lower in the latest round of bidding, but stopped short.

"We shouldn't lead the sector into a vicious cycle, where firms won't be financially strong enough to buy equipment or invest in research and development," Tse said. "We did it in the first round to heed the country's call, but for the second round we have to take the future of the sector into consideration — if we had done it again, the negative impact would have been huge."
The company, whose ambition is to become a global pharmaceutical champion like Pfizer, sees revenue contribution from innovative drugs rising above 50% in the next five to 10 years, up from about 20% now. Tse also expects the company to release 1 to 2 innovative drugs annually from 2021; it has about 38 in clinical trials.

Sino Biopharmaceutical is the best performer on Hong Kong's Hang Seng Index this year, with shares gaining 114%. Its strategy to disengage from the national price war seems to have been cheered by investors: its stock has risen 5.3% since the bidding exercise last month, while Fujian Cosunter Pharmaceutical Co. — one of the local drugmakers who won the contract for entecavir — has dropped 5.4%. (Source:Bloomberg)