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SEPTEMBER 24, 2006

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THE WEEK

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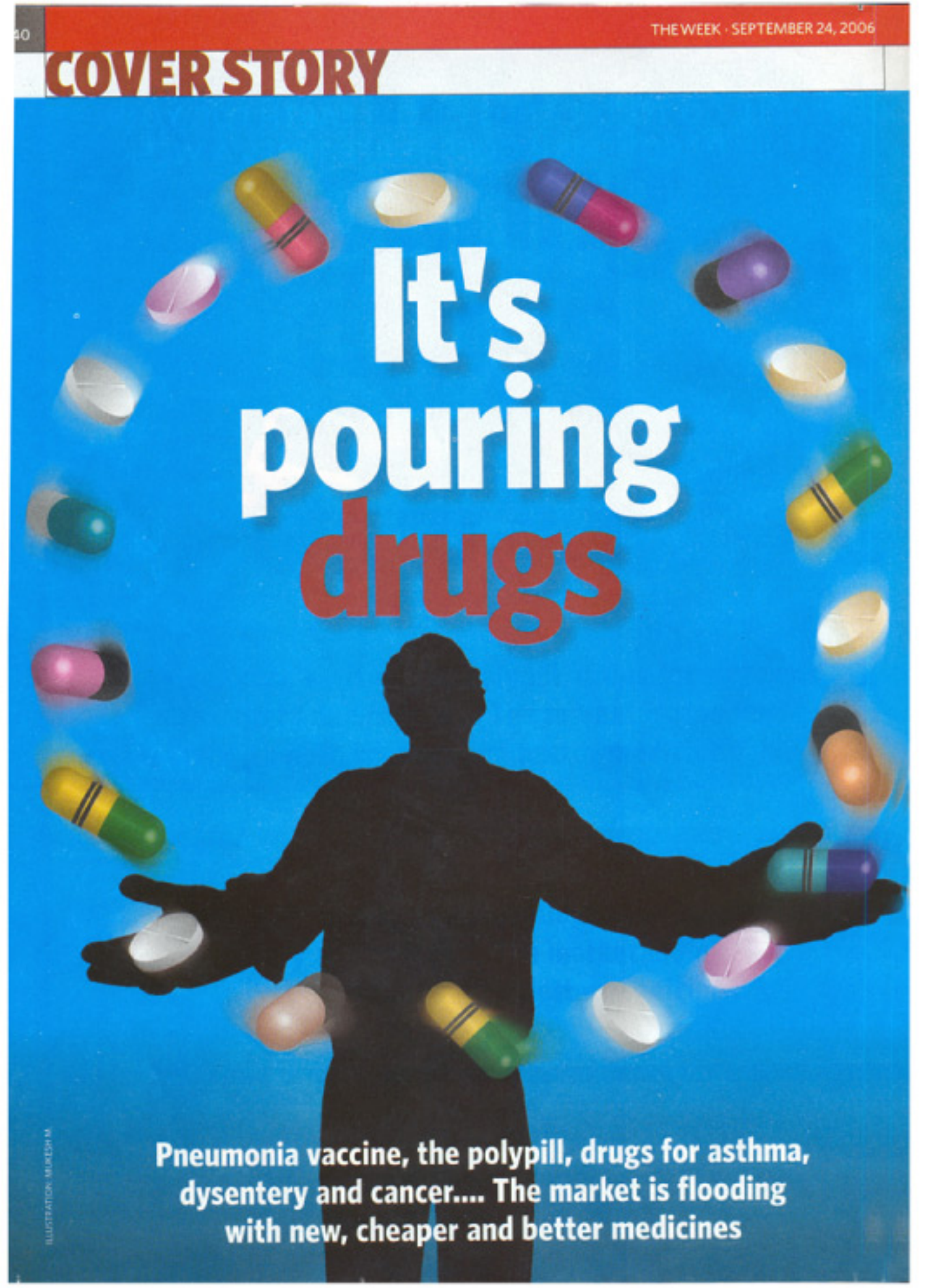
Most awaited DRUGS

Indian companies get ready to serve **better and cheaper**
medicines for asthma to cardiocare and cancer



Polypill to nanotech: The changing treatment

COVER STORY



It's pouring drugs

Pneumonia vaccine, the polypill, drugs for asthma, dysentery and cancer.... The market is flooding with new, cheaper and better medicines

By Kavita Bajeli-Datt

Abypass last December at Bangalore's Wockhardt Hospital & Heart Institute has not changed art collector Harish J. Padmanabha one bit. His passion for art and civic issues remains intact, and so too his craze for automobiles. "I am busier than before the surgery," says Padmanabha, 59, proudly pointing to his Husain and Souza. The polypill coming soon from Hyderabad's Dr. Reddy's Laboratories is probably designed with busy bees like Padmanabha in mind.

One of its kind, the polypill is a combo—a beta blocker, aspirin (blood thinner), cholesterol reducing statin and an ACE inhibitor for hypertension, medicines prescribed for patients with cardiovascular disease, all rolled into one. All that Padmanabha would have to do is pop one pill instead of four! "A four-in-one drug is welcome. Especially if it is once a day," says Padmanabha. "In that case, I may not miss out on the doses." If the combo does work, polypill would be a blessing for India, which is on the brink of a heart disease epidemic. "It provides an opportunity to treat more people and to use this in the prevention of heart dis-



A heart for art: Harish J. Padmanabha (with family) welcomes the polypill

ease," says Dr A.K. Abraham, cardiologist at Indira Gandhi Cooperative Hospital, Kochi.

There is more good news for Indians. More than half a dozen Indian companies are in the race to produce and market medicines, including those already available in the west, at home. A few of these are on the pharmacist's shelves already and some are on the launch pad. Merck India has introduced Erbitux, a monoclonal antibody against colorectal cancer; India reports 35,000 cases of this cancer every year. Ashima Das Sharma of Kolkata may know little about medicine. But having survived cancer of the rectum almost 14 years ago, the 66-year-old

is happy that there is one more treatment option.

Wockhardt's Vitix gel for leucoderma is expected in a few months. Baxter has brought out Extraneal for end-stage renal disease and crotefemer for diarrhoea from Glenmark is slated for a 2008 launch. Bangalore-based Biocon's BIOMab EGFR, out on September 17, is "India's first indigenously developed monoclonal antibody" for head and neck cancer.

What's more, over 60 molecules to treat other common ailments are in various stages of development at labs across the country. These should be ready by 2010 provided the clinical trials show good results. Says Dr Swati Piramal, director-strategic

Before the launch

Phase 1

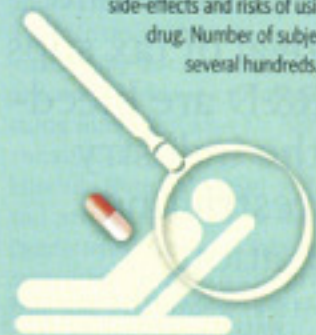
This stage involves introduction of a new drug into healthy humans. To determine the metabolic and pharmacological actions of the drug, the side-effects and effectiveness. Evaluates drug metabolism, structure-activity relationships, and the mechanism of action in humans.

Number of subjects—20 to 50.



Phase 2

Controlled clinical studies for preliminary data on the effectiveness of the drug for subjects with the disease. Objective: To determine the short-term side-effects and risks of using the drug. Number of subjects—several hundreds.



Phase 3

To gather additional information about effectiveness and safety. Provides a basis for extrapolating the results to the general population and putting that information in the label. Number of subjects—several hundreds to several thousands.



RESEARCH & DEVELOPMENT

CANCER

Chasing the crab

Phoolmati Devi, 70, ignored her pelvic pain till, a few months later, she started bleeding. She consulted Dr Amit Bhargav, oncologist at MaxHealthcare, Delhi, who found a growth in her cervix. "It was growing and touching the pelvic bone," said Bhargav. "She was in stage III B. She has already undergone two cycles of chemotherapy and has to do another four rounds. Radiotherapy is also needed in her case."

In India, around 8 lakh cases of cancer are reported every year; half of them succumb to the disease. Cancer incidence is expected to double by 2020, because of changing lifestyle, industrialisation, indiscriminate use of pesticides, adulterants, and tobacco and drug abuse. The worry is that many women are not aware of cervical cancer, despite its being the most reported cancer in India (1.4 lakh annually), followed by cancers of the breast (80,000) and mouth (70,000).

"New cost-effective cancer drugs based on herbal derivatives are being developed," said B.C. Das, director of the Institute of Cytology and Preventive Oncology, Noida, which has an annual research budget of Rs 10 crore. "There has been a tremendous boost in research in life sciences and medicine in the last decade. Many centres in India are now doing pio-

neering research. In many aspects we are world class."

The institute is working on therapeutic plant derivatives and traditional medicines described in ancient texts. "For the first time, we showed how curcumin derived from turmeric can act as an anti-HPV molecule and how it can be used for treatment of cervical cancer," said Das.

HPV (human papilloma virus) causes cervical cancer. India has signed an MoU with Merck, a US-based company whose FDA-approved vaccine called Gardasil will undergo clinical trials in India. GlaxoSmithKline, too, has a vaccine for cervical cancer.

At \$500 for a three-dose regimen, the vaccines are expensive. "Several groups in India are trying to develop cost-effective HPV vaccines," said Das. "We are also in the process of developing HPV DNA vaccine."

Dabur is working on a new compound with anti-cancer activities, said Das. It recently began producing Taxol, which is extracted from the leaves of *Taxus baccata* grown in Almora, Uttaranchal. The company is developing better methods of delivering this drug for breast cancer.

But for patients like Devi the only hope is low-cost early-detection methods so that they can reach the doc before it is too late.



K.K. VINAYAN

alliances, Nicholas Piramal India: "India has the potential. We have to keep on trying despite failures." India already leads in the production of low-cost pharmaceutical ingredients and generics. The buzzword is innovation and not imitation, as Dr R.A. Mashelkar, director-general of the Council of Scientific and Industrial Research (CSIR), says.

The activity in asthma care should be of interest to asthma patients like Rajesh Maheshwari—about 2 crore in India. The 50-year-old Delhi executive has been living with asthma since childhood and goes for the inhaler whenever he feels breathless. A new molecule GRC 3886 brewing in the labs of Glenmark Pharmaceuticals, Mumbai, is touted to have zero side-effects. Ranbaxy recently launched Avesa inhalation capsules. Earlier this year, the pharma giant came out with Osonide inhaler.

Four years from now, Ranbaxy, the largest Indian pharma company with 170 generic products to its credit, hopes to apply for US Food and Drug Administration approval of its anti-malarial drug RBx 11160. Developed in collaboration with Medicines for Malaria Venture—a Swiss non-profit organisation—at Ranbaxy's highly fortified Gurgaon lab, the drug is in the phase II trials, and is expected to be cheaper than existing medicines. The most effective anti-malarial



Price control and removal of tax sops for R&D are bleeding the industry and restricting innovation.

VINAY PINTO, EXECUTIVE DIRECTOR, WALLACE PHARMACEUTICALS

No. 1 by 2020

By Dr R.A. Mashelkar



The next century belongs to India. India could become an innovation hub for global health. By 2020, if it plays its cards right, India can become the world's number one knowledge production centre, creating not only valuable private goods but also the much-needed public goods that will help the growing global population suffer less and live better.

India has an edge over China in the pharma scene, thanks to its three Ds. India has democracy, which allows one to think freely and act. This enhances creativity. The second is demography; 55 per cent of India's population is below the age of 30. And it is the younger people who are involved in innovation. The third is diversity of culture and tradition. This improves creativity.

Over the past few years the budget for science and technology has steadily gone up. The average has been 15 per cent a year. India's R&D budget is now \$6 billion. The department of Science and Technology has been the biggest beneficiary in the past three years.

Indian drug and pharmaceutical

recovered from the disease of the lungs after hospitalisation for nine days. "Invasive pneumococcal disease [caused by bacteria *Streptococcus pneumoniae*] can cause life-threatening illnesses," says Dr Nitin Shah, consultant paediatrician at P.D. Hinduja National Hospital, Mumbai, and president of Indian Academy of Paediatrics. He feels that in today's environment, there is a need for a vaccine like Prevenar, which is brought to India by the Mumbai-headquar-

terted Wyeth. Already available in 75 countries, Prevenar will protect against pneumonia, meningitis and bacteremia. "It will not only protect children from critical diseases but also reduce the disease burden in India," says Ranga Iyer, managing director of the company.

companies have increased their R&D spending by 400 per cent in the past four years. There is a new wave of innovation and drug discovery; now we are not for imitation. We should use cheaper and smarter ways to find new drugs. Today the cost of new drug development is \$1.5 billion. India is trying to build a golden triangle linking traditional medicine, modern medicine and modern science. By taking clues from traditional medical practices, researchers are doing a sort of reverse pharmacology, which is showing great promise. The treatment for psoriasis through reverse pharmacology (in phase II human clinical trials) is expected to take five years and cost \$5 million. If successful, the resulting treatment will be priced at \$50, in contrast to the new \$20,000-antibody injection treatment developed by the west.

We are looking at 20 diseases. Many drugs like the TB molecule, Lysostaphin [for staphylococcal infection], herbal formulations for arthritis and diabetes, and herbal Hepato-protectives are in different stages of testing. All this has been possible through the New Millennium Indian Technology Leadership Initiative, which is a public-private partnership programme [in R&D, funded by the government].

Mashelkar is director-general of the Council of Scientific and Industrial Research.

As told to Kavita Bajeli-Datt



For the grabs: Dr. Reddy's has a few new drugs up its sleeves

drugs currently in the market are the Artemisinin-Combination Therapies (ACTs). "Artemisinin-based drugs are effective, but these naturally derived drugs are costly to prepare and are beyond the reach of millions of malaria victims in poor countries," says William N. Chairman, scientist at Monash University, Australia. "RBx 11160 is an impressive anti-malarial at a more affordable cost." That should be music to millions of Indians like Ravi Malhotra who are constantly exposed to the disease through mosquitoes that carry the malaria-causing parasite Plasmodium.

Malhotra contracted the infection while in Rajasthan. Back home in Delhi, he consulted Dr Sandeep Budhiraja, head of internal medicine at MaxHealthcare, when he began sweating and shivering. Malaria claims more than one million lives every year. In the developing countries the majority of its victims are children below five and pregnant women. The disease is estimated to kill one child every 30 seconds and cause up to 600 million new infections worldwide annually. Malhotra survived thanks to timely intervention.

It was prompt action that saved Sameer Joshi from pneumonia; the 25-year-old Mumbaikar recently

recovered from the disease of the lungs after hospitalisation for nine days. "Invasive pneumococcal disease [caused by bacteria *Streptococcus pneumoniae*] can cause life-threatening illnesses," says Dr Nitin Shah, consultant paediatrician at P.D. Hinduja National Hospital, Mumbai, and president of Indian Academy of Paediatrics. He feels that in today's environment, there is a need for a vaccine like Prevenar, which is brought to India by the Mumbai-headquar-

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New drugs: On the shelves and in the pipeline

Extraneal

Drug for end stage renal disease

BAXTER

Launch: September

Chronic kidney disease, often related to diabetes or hypertension, is the third most common non-communicable disease in India with over 1.5 lakh new patients every year. Extraneal removes more fluid during dialysis because it uses a novel osmotic agent, which is a polymer of glucose.

Says Dr Sandeep Mahajan of All India Institute of Medical Sciences, Delhi: "Extraneal reduces metabolic side-effects."

Erbix

Drug for colorectal cancer

MERCK

Price: Rs 16,908 a vial

Out in the market

Colorectal cancer is the third most common malignancy worldwide. In India, about 35,000 new cases are reported every year. Erbix is the first approved monoclonal antibody that inhibits the growth and proliferation of cancer cells by binding to the epidermal growth factor receptor, the molecule on the surface of the cell that stimulates growth.

Prevenar

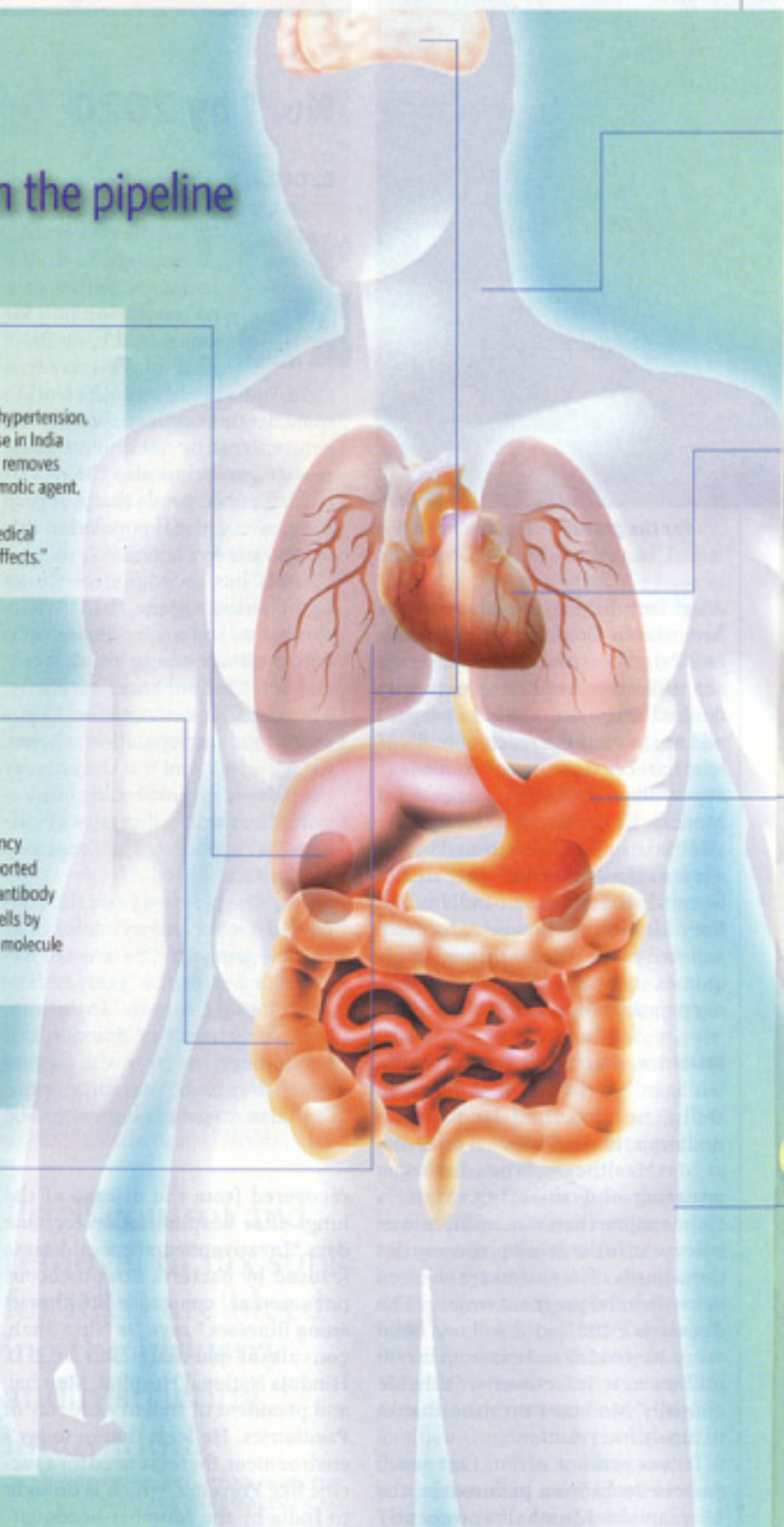
Vaccine against meningitis, pneumonia, bacteremia

WYETH

Price: Rs 4,000 per shot

Out in the market

The first and only vaccine for infants against diseases like meningitis, bacterial pneumonia and bacteremia (bacteria in the blood), caused by the bacteria *Streptococcus pneumoniae*. The vaccine, which is already available in 75 countries, is administered in three doses to children below 2 years.



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BIOMab EGFR**Drug for cancer**

BIOCON

Launch: September 17

A monoclonal antibody for the treatment of cancer of the head and neck. India's first indigenously developed monoclonal antibody, according to Biocon.

Polypill**Drug for heart disease**

DR. REDDY'S

Price: Not yet fixed

Launch: In a few months

Polypill is many drugs rolled into one. It is a combination of a beta blocker, aspirin (blood thinner), cholesterol reducing statin and an ACE inhibitor for hypertension, all prescribed for people with heart disease.

Crofelemer**Drug for diarrhoea**

GLENMARK PHARMACEUTICALS

Price: Yet to be decided

Launch: 2008

Crofelemer, a drug for AIDS diarrhoea, infectious diarrhoea and paediatric diarrhoea, is in the Phase II trial stage.

Glenmark signed a development and commercialisation agreement with Napo Pharmaceuticals last year and will market the drug in over 140 countries, including India.

Vitix**Gel for vitiligo**

WOCKHARDT

Price: Not yet fixed

Launch: December 2006

Vitiligo, or leucoderma, is a skin disorder affecting 1-2 per cent of the global population. The patient develops white patches caused by localised loss of pigment. Wockhardt has signed an agreement with Life Science Investments, UK, to manufacture and market Vitix in India.

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SANJAY ARAJAWAT

Trial, trial, till success: Ranbaxy's anti-malarial drug is expected to be cheaper than the existing ones

are getting more confident, gaining knowledge, better facilities, skills and clinical research, and better methodology. It is mind-boggling that in a short period we would be coming out with so many drugs. It is not happening in any developing country or even the developed ones."

Till about 30 years ago, the industry was struggling to make even the most basic drugs. Nobody had probably wondered about the potential of the sector till Dr K. Anji Reddy, founder chairman of Dr. Reddy's, came out with a new compound called glitazone in 1998. Found to help the body use insulin better, the drug failed in the third phase of trials in 2002. "It could have been a path-breaking drug," says Reddy. "But I didn't despair. I knew it would be a matter of time before we came out with a new drug."

Innovation and discovery require strong research and development. And armed with a budget of \$6 billion (Rs 27,692 crore) for R&D, India's pharma sector has been pumping in resources like never before. In fact, India has the largest number of FDA-approved manufacturing facilities outside the US. "The acquisition of new and niche technologies is an integral part of Ranbaxy's strategy to enhance capabilities and move up the value chain," says Ramesh Adige, executive director. Three hundred of its 1,100 scientists are working just on new drugs.

India's fourth largest pharma com-

pany, Nicholas Piramal, has focused research on select areas—anti-cancer, anti-inflammatory, anti-diabetic and anti-infective. "The R&D centre of Nicholas Piramal is world-class," says Ganguly. The company, whose anti-cancer molecule NP102 has passed the first phase of trials, has acquired the high throughput screening facility (which can scan small molecules and genes). Biocon has invested Rs 650 crore on its Biocon Park, claimed to be "India's largest integrated biotech hub". "Indian pharmaceutical companies have increased their R&D spending by 400 per cent in the last four years," says Mashelkar, who is also president of the Indian National Science Academy. "Though it is obviously not on par with the west, pharma companies are spending 8 to 12 per cent on research," says Ganguly.

Since production of a new drug is a long (10-12 years) and expensive (up to Rs 4,600 crore) affair, many pharma majors are outsourcing part of the process to foreign companies to cut costs and speed up production. Glenmark Pharmaceuticals, which has outsourced trials for a new molecule, will in return get not only money for the molecule but also the right to market it in some countries. For crofelemer, the company signed an agreement with the US Napo Pharmaceuticals last year for developing the drug and marketing it in over 140 countries including India. Wockhardt has signed an in-licens-

RESEARCH & DEVELOPMENT

TUBERCULOSIS

Quicker, shorter

Life for Delhi marketing executive Neeraj Singh was all about meeting deadlines. So much so that the 27-year-old ignored the persistent cough that came with a slight fever and weakness till he could no longer work. A local doctor told him to get his chest X-rayed. By then he had lost weight and appetite. When sputum and blood samples tested positive for tuberculosis, Dr Rajesh Chawla, senior consultant in respiratory medicine and critical care at Indraprastha Apollo, whom Singh consulted, prescribed a four-drug regimen—Rifampicin, Combutol, INH and Pyrizinamide.

Singh developed side-effects—drowsiness and change in the colour of urine to red. “Patients see these side-effects and stop taking the medicines, which is dangerous,” said Chawla, who gave him drugs to counter the side-effects. “They should complete the six-month cycle.”

Doctors like Chawla can put their worries to rest once the “first new molecule to treat TB since 1963” is out. Phase II trials now on at the TB Research Centre in Chennai will also look at shortening the duration of the therapy to four months.

The drug is significant because TB claims 5 lakh lives every year in India. The WHO-recommended DOTS was introduced after the National TB Control Programme of 1962 flopped.

That only poor people contract TB is a misconception, says Chawla. “People with a low resistance also get it,” he says. “Most of us are so busy with work that we tend to skip meals and that leads to low resistance.”

A lot of research is happening in India on TB. Says Dr P.R. Narayanan, director of the Chennai centre: “Basic research for developing new drugs, diagnostics and vaccines is in progress as we now know the genome of the TB bacillus. Operational research for sustaining and improving the TB control programme is getting a lot of attention. Epidemiological research to study the annual risk of infection

and assess the impact of DOTS is also under way.”

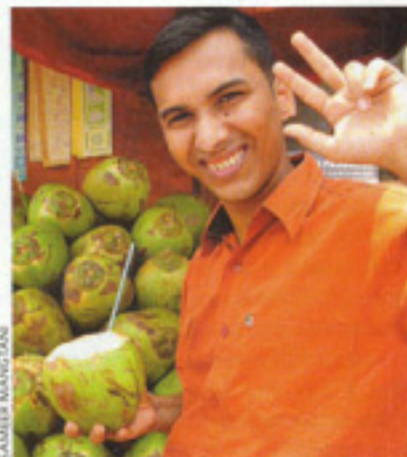
But the availability of drugs alone will not ensure victory over TB. “What is required is the widespread use of standardised regimens under supervision,” says Narayanan. And this, he feels, is possible only through health education besides sustainable public-private partnerships. “Transmission of disease can be brought down only by treating all infectious cases in the community,” he says. “This will reduce new infection. Improved quality of life and increased hygiene and infrastructure will speed up the process of control of TB.”

A TB drug with a shorter duration of therapy is in the pipeline at AstraZeneca Pharma India. Says Bhasker Iyer, managing director: “The new drug will reduce the duration of therapy, can be administered along with anti-HIV drugs and is also active against latent mycobacteria.”

Singh has decided to take a break and listen to his body. “I have left my job because it was hectic,” he says. “I will get fit and then start life again.”

ing agreement with Life Science Investments, UK, to market Vitix. “This is part of Wockhardt’s initiative to bring new advances to India,” says Habil Khorakiwala, chairman. Biocon’s research subsidiary Syngene International has tied up with Swedish Innate Pharmaceuticals to develop virulence blockers—a new class of drugs—against bacterial diarrhoea. Collaboration is expected to bring down the cost and speed up trials and production.

Home-made drugs are likely to be cheaper. For instance, Prevenar at Rs 4,000 in India is Rs 6,000 less than its price in the west. While imported monoclonal antibodies come for around \$15,000 (Rs 692,299), Erbitux from Merck is available in India at Rs 16,908 a vial. The price of the polypill, too, would likely be less than that of the four drugs combined.



Aye for new drugs: Sameer Joshi

The flip side of the hectic activity in the sector is cut-throat competition. There is also a shortage of researchers, say experts. “On top of that, regressive and illogical government policies like price control and the removal of

tax sops for research and development are bleeding the industry and restricting innovation through R&D,” says Vinay Pinto, executive director, Wallace Pharmaceuticals, and executive committee member of the Indian Drug Manufacturers’ Association.

Associating with ICMR is one way of cutting down the number of years and the cost. ICMR came out with Miltefosine for black fever in three years. Says Ganguly: “By associating with us the expenditure would come down and that means affordable drugs. The drugs would be available in the market and could be part of the national programme.”

How many of these drugs will survive the tests—in the lab and the market—is for time to tell. Watch this space.

With N. Bhanutej, Tathagata Bhattacharya and Rohini Teresa Mathew

Smart shots

GenNext technologies facilitate better therapies with fewer side-effects

By Dr Jame Abraham and Shyla Jovitha Abraham

In 1928, when a doctor returned to his lab in St Mary's Hospital in London after a long holiday, he found mould in the culture plates that he had left unwashed. His frustration turned into curiosity when he noticed that there was no bacteria around the mould. This led to the discovery of one of the most successful medicines in the twentieth century. The medicine was penicillin and the doctor was Alexander Fleming.

But now drugs are discovered neither by chance nor by a lone scientist. A scientist in Boston identifies the root cause of a disease, which turns out to be an excellent target for therapy. A Bangalore computer scientist develops a virtual model of that target. A group in Singapore develops a chemical compound which can hit the target. Doctors in Bethesda and Manchester test the drug on animals. If the tests are successful, large university hospitals in Los Angeles and Lyons start human trials.

Advancements in bio-informatics and the human genome project are changing the landscape of drug discovery. Says P.M. Ajayan, professor of materials engineering at Rensselaer Polytechnic Institute, New York: "Properly engineered nano-systems could revolutionise many fields including medicine, since we would have unprecedented control in manipulating these systems. The health sciences would also benefit indirectly from the improvements in nanotechnology-enabled instrumentation and probing systems and the incredible advances in electronics via the nano and molecular electronics revolution."

Nanotechnology deals with the engineering of tiny machines of

nano scale—nano is one billionth of a metre. Scientists can use this technology to develop extremely small vehicles that can deliver drugs to the targets.

Johnson & Johnson has finished phase III clinical trials for injectable paliperidone palmitate, a drug for schizophrenia, using a proprietary nanotechnology. This is an old drug which had problems in reaching the brain. The nanotechnology drug delivery system will also ensure that the dosage is appropriate.

Chemotherapy through the vein can destroy cancer cells. But, it kills normal cells, too. With nanotechnology, we can develop a system that delivers the right dose, but only to the tumour. Research is on to develop advanced nanotechnologies for early detection of plaque at a molecular level. Plaque could block blood vessels and cause heart attack and stroke.

The other advancement is the human genome project, which decodes the genetic make-up of an individual. An important risk factor for many diseases like heart disease, diabetes and cancer is in our genes. The reason two patients with the same kind of cancer respond differently to the same treatment lies in their DNA. "Within a decade or two, it will be possible to sequence one's entire genome for a laboratory cost of less than \$1,000. If this proves true, one can imagine how not only research, but also clinical care, may change dramatically," says Dr Francis Collins, director of the human genome project at National Institutes of Health, USA.

Cancer therapy has moved into the targeted therapy era with such highly effective drugs as imatinib (Gleevec) for chronic myeloid leukaemia and trastuzumab (Herceptin)



Step by step: Dr. Reddy's lab; drug discovery is a planned and complex process

for breast cancer. Dr M.V. Pillai, clinical professor of medicine at George Washington University and director of Virginia Oncology Care, USA, explains targeted therapy with the analogy of Arjun winning Draupadi in the Mahabharat by shooting a fish in the eye by looking at its reflection in the water. The modern cancer researcher is like Arjun, says Pillai.

Destroying blood vessels that feed the tumour is another area of targeted therapy. Research by Rakesh Jain, professor of tumour biology at Harvard Medical School and Massachusetts General Hospital, has led to many therapeutic advances in this field. Bevacizumab (Avastin) is a drug which kills the tumour by cutting blood supply.

The US Food and Drug Administration approved Pfizer's Exubera, the first inhaled insulin, early this year. Newer drugs like Galvus and Januvia are now in a race to become the first to raise the level of the protein called glucagons-like peptide. These drugs are similar to exenatide (Byetta), which can prevent very low blood sugar and even help patients lose weight.

Dr Abraham is medical director, Mary Babb Randolph Cancer Center, West Virginia University.