New Zealand Holds Hearing on Implications of Genetic Engineering

New Zealand’s Royal Commission on Genetic Modification held a meeting in June with the country’s experts to discuss the various aspects of genetic engineering, particularly the ethical concerns.

The keys areas covered at the meeting include:

- The purpose of genetic engineering and its products, and how and where these will be used;
- Review of evidence and the level of uncertainty of the present and future applications of genetic engineering techniques;
- The risks, benefits and opportunities from the use or avoidance of genetic engineering technologies and products, and where they are likely to be distributed;
- The international legal obligations New Zealand would face and the liability issues;
- Main areas of public interest in genetic engineering, including issues relating to public health, environment, biosafety, economy, culture and ethics;
- Implications on the Treaty of Waitangi. This refers to an agreement drawn up in 1840 between the British settlers and the indigenous Maori people to live peacefully, particularly relating to the natural resources in New Zealand.

Being an agriculture-based economy, New Zealand is understandably concerned about the implications of genetic engineering. Until the Royal Commission make their recommendations, the government had imposed a “voluntary” moratorium on the field testing of genetically engineered plants and animals. At the meeting, the Commission did not discuss the “modern standard breeding techniques” used in biotechnology, such as cloning, mutagenesis, protoplast fusions and monoclonal antibodies. A public meeting has been scheduled in end-July to hear the public’s views, and the Commission is not expected to make any decisions until March 2001.

India May Privatize Healthcare Services

The Indian government has proposed to privatize healthcare services in the country. This will be done through joint ventures with private companies in the healthcare sector. The proposed plan, which includes privatization of major hospitals through a bidding process, may later be extended to include new district hospitals yet to be set up. Privatization is expected to help improve hospital service, as well as generate some income for the hospitals. The government, however, has stressed that charges for treatment will not be allowed to be too high. The health ministry is currently preparing the necessary guidelines with input from the private sector.

Franklin Templeton Launches Life Sciences Fund in Singapore

Life sciences is tipped to be next big thing to impact the world economy, whose magnitude may possibly surpass even the Internet revolution in the last decade. With the cracking of the genetic code by the Human Genome Project, development of pharmaceutical and drug products are expected to accelerate.

Given the availability of resources such as the genome library, medicine will be practiced in a different form — treatment will be at the genetic levels using tailor-made drugs. Large projects are being established to develop more effective drugs and novel ways of taking them, and more quickly too. As such, more money is required to fund these projects.

Franklin Templeton Investments launched Singapore’s first life sciences fund on 26 June 2000. The Franklin Life Sciences Discovery Fund seeks capital appreciation by investing primarily in equity securities of biotechnology companies and discovery research firms around the world. This fund is an extension of the US-registered Franklin Biotechnology Discovery Fund, which gained 98 percent in 1999 and was named Number One Biotech Fund in 1999 by Lipper Analytical Services.

Although there are now over 1500 biotech companies in the US, only fourteen are in the black. Currently, biotech companies are spending more than they are earning because drugs normally take ten to fifteen years to develop and gain approval from the Food and Drug Administration. Biotech stocks are also very volatile — while some stocks are now worth more than 800 percent their list price, and plunges of the same magnitude have also been experienced.

Asia-Pacific Biotech News met up with Mr. Kurt von Emster, the fund manager of the Franklin Templeton Life Sciences Discovery Fund, to find out his views on the biotech industry and his advice for investors.

Is investing in biotech stocks profitable?

Biotech stocks currently take up one-tenth of the overall technology stocks. At the moment, only fourteen firms are profitable, but Mr. von Emster predicted that this number would increase to about twenty by the end of this year. Pharmaceutical companies typically take ten years to bring their drugs to the market, but with the advancements in technology, introduction of drugs at a much faster rate can be expected.
The high volatility of biotech stocks is well-known. 250 percent annual returns are very likely, but the reverse is also true. However the general trend is upwards and Mr. von Emster is confident that with the right strategies in choosing stocks, positive returns on the investment funds are not difficult to achieve.

**What are your strategies?**

Firstly, single-product companies would not be a good choice. Case studies of a potential drug to cure cancer but was subsequently rejected by the FDA at the third stage due to harmful side effects are common. Mr. von Emster recommended stocks of large and established companies which have a wide portfolio of products. Even if one product is rejected, there are still many more that the company can make money from.

Secondly, drug discovery companies that have products which have successfully passed clinical trials on humans hold good potential. Mr. von Emster is constantly on the look-out for companies that have products waiting to be launched. Stocks of companies whose products are well-received would definitely increase in value.

The last of the three-legged strategy include smaller companies that do not appear to have “wonder drugs” in their portfolio. Companies that manufacture molecular devices or medical equipment for use in pharmaceutical companies and hospitals would fall into this category.

### Are biotech companies in Asia-Pacific worth investing in?

Mr. von Emster noted that compared with the US, the biotech industry here is still in its infancy. Presently, he has considered investing in a few Japanese pharmaceutical firms.

The decision to launch the Life Sciences Discovery Fund in Singapore was deliberate. The Singapore government’s support for biotech is an important factor. The move to inject an additional S$1 billion (US$585 million) to the local biotech industry and research confirms Templeton’s decision. However, investment in Singapore companies is forthcoming — only about five years later.

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**Ranbaxy Scales Up Ciprofloxacin Production**

India’s leading pharmaceutical company, Ranbaxy Laboratories, has scaled up the production of the novel drug delivery system of the anti-infective drug ciprofloxacin that it is developing for Bayer AG of Germany to commercial size. The company, which initially produced experimental quantities of only 100 grams of the drug, is now able to produce up to 300 kilograms in its plant.

Bayer is currently carrying out phase I trials of the drug in the US with samples from the scaled-up batches. If the results are satisfactory, Bayer will pay Ranbaxy US$5 million as milestone payment in September this year. Ranbaxy will receive an additional sum of US$10 million once the Food and Drug Administration (FDA) approves the investigative new drug application, which will take about three months upon filing.

After phase I trials have been completed, the drug will enter a combined phase II and phase III trial. This will take about 12 months to complete. Ranbaxy will receive another milestone payment from Bayer once a new drug application is filed following the combined phase II–III trials. While Bayer carries out the clinical testing in the US, Ranbaxy will also be conducting similar tests in India.

Ranbaxy is targeting global sales of over US$500 million this year. Although it recorded only three percent sales growth in India for the first quarter of this year, it is targeting to achieve double-digit growth by year-end.

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**SRL to Provide Virco’s HIV Resistance Test in Japan**

The Virco Group has signed an agreement with SRL Inc., to assign the latter rights to provide Virco’s HIV resistance monitoring services in Japan.

Virco’s testing services use molecular and genomic techniques to detect the changes in the genetic code of patients, as well as to measure the sensitivity of the HIV to certain drugs. By comparing with Virco’s database, which holds 70 000 genotypes and phenotypes, the resistance of the HIV to the drugs can be accurately forecasted.

There are an estimated 7000 people living in Japan who are infected with AIDS. Some treatments presently available appear to be losing their effect as the HIV develops resistance to the drugs. Doctors are reportedly using these tests more frequently to select the best combination of drugs for each individual patient.

SRL, a Japanese laboratory services company, is excited about the impact of the tests on the pharmaceutical industry in Japan. SRL spokesman, Katsuya Oikawa said, “We anticipate that the routine use of resistance testing alongside viral load testing and our other HIV services will improve the outlook for Japan’s HIV-infected population and even save healthcare resources through avoiding the use of ineffective drugs.”

The Virco Group is a research-based biotechnology company which applies technologies in molecular biology, genomics, automation and electronic data processing to the diagnosis and disease management of HIV, other infectious diseases and cancer. It was founded in Belgium in 1996 and has offices and research facilities in UK, US and Ireland.
Bio Medical Laboratories to Use Third Wave’s Technology in Research

One of Japan’s largest clinical reference laboratories, Bio Medical Laboratories (BML) Inc., will utilize Third Wave Technologies Inc.’s proprietary Invader® operating system in its clinical studies. Under the terms of the agreement, BML will use Invader® in large-scale collaborative genotyping studies in the arteriosclerosis field, and eventually introduce it as a standard for DNA analysis in Japan.

The Invader® technology is based on a homogenous, PCR-free format. Its features include high accuracy, automation, scalability and adaptability to other applications. The collaboration with BML is but one of many with other leading genome research institutes, such as Sanger Center and Stanford, Cambridge and Oxford Universities. These have already adopted the technology for large-scale single nucleotide polymorphism and gene expression studies research in the genetic basis of common diseases. The results will then be translated into improved patient care.

Third Wave is an US-based company that develops and provides DNA and RNA analysis technologies for use in genome research, pharmacogenomics and clinical applications.

BML is one of the most influential laboratories in Japan which serves more than 100,000 patients each day. It provides a wide range of laboratory tests such as biomedical and hematologic tests, and specialty tests such as cellular immunological and DNA genetic analyses.

Shijiazhuang Pharmaceutical and Unigene Labs Establish Joint Venture

China’s Shijiazhuang Pharmaceutical Group Company Ltd. will establish a joint venture with Unigene Laboratories, Inc. to manufacture and distribute Unigene’s injectable and nasal calcitonin products in China. Depending on how well the drugs are received in China, the agreement will extend to cover other Asian countries.

The Chinese regulatory authorities have earlier granted Unigene an import license for injectable and bulk calcitonin. A new application has been submitted for the joint venture. Upon approval of the application, Unigene will own 45 percent of the joint venture and have market exclusivity for similar products for the next six years.

In the first phase, the joint venture will market Shijiazhuang’s existing injectable calcitonin products and Unigene’s products will be added to the portfolio later this year. In the second phase, a state-of-the-art facility will be set up in New Jersey to fill injectable and nasal calcitonin products containing bulk calcitonin. A new plant will be built in China to manufacture the bulk drug during the third phase.

Calcitonin is a naturally occurring peptide hormone that helps to prevent bone loss and reduce the incidence of bone fractures. China has approximately 50 million people suffering from osteoporosis and reportedly 15 million fractures a year. According to the Shanghai Medical Journal and Chinese medical experts, 90 percent of Chinese over 60 years old suffer from osteoporosis, leading the government to list it as one of the top three health priorities. Therefore, the joint venture not only holds vast potential to the companies, it also promises to bring relief to the people.

Unigene is an US-based biopharmaceutical company which undertakes research and production of therapeutic peptide hormones. Unigene’s President, Dr. Warren Levy expects to benefit from short-term product sales and a strong marketing presence in China, which is one of the world’s largest osteoporosis markets.

Shijiazhuang was chosen as its business partner because it is one of the largest and most profitable pharmaceutical companies in China, with annual sales exceeding 2.5 billion yuan (US$300 million). It is a principal investor in more than 20 other joint ventures and is the majority shareholder of Chinese Pharmaceutical Enterprise and Investment Co., which is listed on the Hong Kong Exchange.

Shanghai Kehua Signs Distribution Agreement with Response Biomedical

Response Biomedical Corp, a Canadian-based point-of-care diagnostics developer, has recently signed a distribution agreement with Shanghai SIIC Kehua Biotech Co., Ltd. Under the terms of the agreement, Shanghai Kehua will distribute Response Biomedical’s proprietary RAMP™ diagnostic system in China.

When a heart attack occurs, proteins such as myoglobin, troponin I and CK-MB are released into the blood. The RAMP™ system has the ability to detect the presence of these proteins within ten minutes, thus reducing the time and costs involved in diagnosis. It is also a platform from which Response Biomedical develops tests for infectious diseases (e.g. hepatitis), coagulation, diabetes, therapeutic drug monitoring, cancer and hormones. Humberto Reyes, Chairman of Response Biomedical, revealed that the agreement signed in China set the stage for initial international sales of the RAMP™ system and will play a significant role towards the sales in Europe and US.

Shanghai Kehua is the largest reagent manufacturer and distributor in China and has 20 subsidiaries nationwide. The in vitro diagnostics market in China was estimated at US$327 million in 1999 and it is expected to grow at a compound rate of 16 percent annually.

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Indian Company to Market Traditional Medicine in Japan

Indian company, Maharishi Ayurveda Products, which markets ayurveda (traditional Indian medicine) preparations, is all geared to enter the billion-dollar Japanese market for natural and herbal medicine. With this move, it will be the first ayurveda company to operate in Japan. Maharishi has recently been awarded the ISO 9001 quality certification by DNV, a Dutch firm. It is currently in the process of obtaining certification from the Therapeutic Goods Authority of Australia. The US is at present the largest market for Maharishi, which has a network of 6000 trained staff worldwide to dispense its products.

The company’s president, Anand Srivastav, told the Indian Economic Times that Maharishi is targeting a turnover of 12 to 15 million yen (US$0.11 million to US$0.14 million) by the end of the first year of operations. He said that they have been eyeing the Japanese market because the standard of living in Japan is as good as in the US, and also because there is much awareness concerning traditional medicine in Japan when compared to other markets.

Maharishi will be entering the Japanese market with a portfolio of 120 products. This includes a range of food supplements, aromas oils, cosmetics and body care products. Its product for the treatment of diabetes — Glucomap — is expected to be well-received in Japan where more than 20 percent of the population is diabetic. Another product which is expected to receive much attention is “Amrit Kalash.” This product significantly reduces the side effects of chemotherapy and radiation in cancer patients.

Singapore Health Informatics Company Launches IPO

Ezyhealth Asia Pacific Ltd., a Singapore health informatics company, launched its initial public offer (IPO) of 50 million new shares on the Stock Exchange of Singapore on 10 July 2000. The company hopes to raise S$19 million (US$11 million) from the shares, which have a par value of S$0.05 (US$0.03).

Of the total proceeds raised, about 18 percent will be used for the development of healthcare information technology and enterprise application integration infrastructure; 52 percent for working capital requirements in Malaysia and to start up regional operations in South Korea, Hong Kong, the Philippines and Indonesia; and the rest for local working capital purposes. Although Ezyhealth is based in Singapore, it has a long-term overseas expansion plan. Negotiations to set up joint ventures in Malaysia and Korea have already begun.

One of the Ezyhealth’s core business is providing healthcare information technology and online connectivity business group services to clinics, pharmacies and laboratories. The company develops, installs and maintains the software systems to manage activities such as procurement, inventory control and patient/customer database activities. To date, Ezyhealth has installed healthcare information systems in eighteen hospitals in Malaysia, Indonesia and the Philippines.

Ezyhealth also operates two health-related websites. The first, www.ezyhealth.com, enables ordinary consumers to access health and medical information, including information on complementary and alternative medicines. The second, www.drhub.com, is designed for health professionals where they can access the online medical research library, medical news, peer-to-peer medical discussions and buy supplies and equipment, among others.

ALTERNATIVE MEDICINE

UK Doctors Support Acupuncture

The British Medical Association (BMA) would like acupuncture to be made available to patients under UK’s National Health Service (NHS). The association is calling for nationwide guidelines on the use of this traditional Chinese therapy after clinical research has proved that it is effective in easing back and dental pain, migraine, nausea, and vomiting.

A survey of general practitioners (GPs) showed that 58 percent of them had arranged complementary or alternative therapies — predominantly acupuncture — for their patients. Of the GPs surveyed, 82 percent said they have “very little” or only “basic” knowledge of complementary medicine, but half expressed a desire to learn.

The BMA has carried out a two-year study on acupuncture and other complementary and alternative medicines and says they now need to be integrated into the NHS. Among other proposals in the association’s report Acupuncture: efficacy, safety and practice is the compilation of a national registry of all acupuncturists. The BMA also wants to see regulatory procedures for acupuncturists strengthened and recommends better training for GPs about the benefits of the technique and its proper handling.

The BMA report says that there is a need for greater consensus on the part of the government, Department of Health, NHS Executive, the medical profession, and acupuncture organizations on how acupuncture and other complementary and alternative medicine services can be integrated into the country’s healthcare system.

According to Dr. Richard Halvorsen, a GP who has practised acupuncture for 15 years and who is the press officer for the British Medical Acupuncture Society, greater use of acupuncture could save the NHS millions of pounds each year.