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NEWS

Newsletter of Singapore Association of Pharmaceutical Industries

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*OPENING ADDRESS BY*

**DR BALAJI SADASIVAN,**  
MINISTER OF STATE FOR HEALTH AND THE  
ENVIRONMENT AT  
**THE SINGAPORE ASSOCIATION OF  
PHARMACEUTICAL INDUSTRIES**

COLLOQUIUM AND DINNER AT FULLERTON HOTEL  
WEDNESDAY, 30 OCTOBER 2002 AT 8.30 P.M.



*Dr Balaji Sadasivan  
Minister of State for Health and the  
Environment*

Mr John Lepore  
President, Singapore Association of  
Pharmaceutical Industries

Distinguished Guests

Ladies and Gentlemen

1. I am pleased to join you this evening for the Singapore Association of Pharmaceutical Industries Colloquium and Dinner.
2. I note that the Singapore Association of Pharmaceutical Industries (SAPI) has 36 years of formal history dating back to 26 May 1966 and that your association includes all the major pharmaceutical companies concerned with a wide spectrum of pharmaceutical related businesses.
3. Over the years, SAPI has established close and fruitful working relationships with the various medical and allied professional bodies and medical institutions in Singapore. In addition, SAPI has been very supportive of the work of the Health Sciences Authority and the

Ministry of Health. This is to be applauded and encouraged. This evening, I would like to talk about 2 important interfaces between the pharmaceutical industry and the healthcare sector.

4. The pharmaceutical sector is an important and growing contributor to Singapore's economy
5. The Economic Development Board reported that Singapore's Biomedical Sciences industry demonstrated resilience to the global economic slowdown in 2001 and that the Biomedical Sciences industry's manufacturing output grew by 3.2% to S\$6.6 billion last year. The pharmaceutical sector's output of S\$5 billion accounted for 76% of the total Biomedical Sciences manufacturing output. For the month of August this year, the Biomedical Sciences industry chalked up a growth of 77.2% with the growth for the pharmaceuticals and medical technology segments at 91.6% and 17.3%, respectively. The new production capacities introduced in the last quarter of 2001 and the manufacture of a wider range of active ingredients for



*Mr John Lepore  
President, Singapore Association of Pharmaceutical Industries*

pharmaceutical preparations has contributed to the growth in the pharmaceutical industry. Cumulatively, the total output of the Biomedical Sciences industry for the first eight months of this year surpassed that of the same period in 2001 by 59.1%. A weighted 88% of the Biomedical Sciences industrialists expect robust business conditions to remain throughout the second half of 2002.

6. One important interface between the biomedical science industry and the healthcare services is in the area of clinical trials. Clinical trials can contribute to improved patient care because it allows us to rigorously assess the utility of drugs and new treatments for our patient population. Early phase clinical trials also allow our patients more timely access to very new forms of promising treatments. My Ministry has taken active steps to ensure that clinical trials take place under a regulatory framework that assures patient safety and the quality of clinical trial conduct and data, based on internationally recognised standards for Good Clinical Practice. Since the adoption of the Singapore GCP Guidelines in 1998, the number of clinical trials performed in Singapore has increased steadily. More than 160 Clinical Trial Certificates were issued by HSA in 2001, and 146 have already been issued from January to September this year. Of these 146 certificates, 43% are for phase 1 and 2 trials and 47% are for phase 3 trials, reflecting the increasing numbers of early phase studies conducted here.

7. As part of its regular review process, HSA has looked into ways of further enhancing the clinical trials regulatory framework to meet even higher standards for safety, ethics and quality, while streamlining regulatory processes to reduce unnecessary delays in the evaluation

and approval of trials applications.

8. The review is nearing its conclusion. Under the proposed new framework, HSA will assess clinical trial sites and centres and issue licenses to those that meet its requirements. These requirements will particularly focus initially on the verification of hospital ethics committees. The new framework will also more clearly delineate the roles of the hospital ethics committees, HSA and its expert committees, in the evaluation of clinical trial applications. A risk based trial review and approval process will be implemented where the hospital ethics committees will be able to approve low risk clinical trials, starting initially with the phase 4 trials. The hospital ethics committees and HSA will review phase 3 and earlier clinical trials in parallel. Full details of the revised clinical trial framework and the plans for its implementation will be announced in January 2003.

9. The other obvious and important interface between the pharmaceutical industry and the healthcare system is in the provision of safe and efficacious drugs. The Health Sciences Authority has a well-developed system to ensure that medicinal products entering the Singapore market are of high quality and are safe and efficacious. It checks that medicinal products that are imported as well as those that are manufactured locally are of international standards. This will not only increase public confidence in the drugs that are available here but also help locally manufactured medicinal products to be more readily accepted overseas.

10. At the same time, the HSA actively reviews the drugs registered in Singapore, with a view to increased declassification of prescription medicine to 'pharmacy-only' items and from 'pharmacy-only' items to 'over-the-counter' items, in line with well-accepted practices in other developed countries, to expand and improve patient access to medicines.

11. I am happy to note that on both these interfaces, SAPI has been very supportive of the work and initiatives from HSA and MOH. Ultimately, these efforts should translate into better and more affordable treatments for Singaporeans. On this note, I wish you a pleasant evening.

# Innovation for Patients

## Pharmaceutical Research and Manufacturers' Association's (PhRMA) Perspective on Innovation and Health

The dictionary defines “innovation” as “the introduction of something new.” In the pharmaceutical industry, innovation is a long, costly and risky process, but one that can yield magnificent results for patients.

### Innovation and Health

It takes an average of 10-15 years from the time a compound is synthesized in a laboratory until it becomes an approved medicine. There are far more failures than successes, but the successes can touch millions of lives. Ten years ago, for example, there were no medicines to treat Alzheimer's disease. Today there are four approved medicines and 17 more in development. Perhaps one will be a cure.

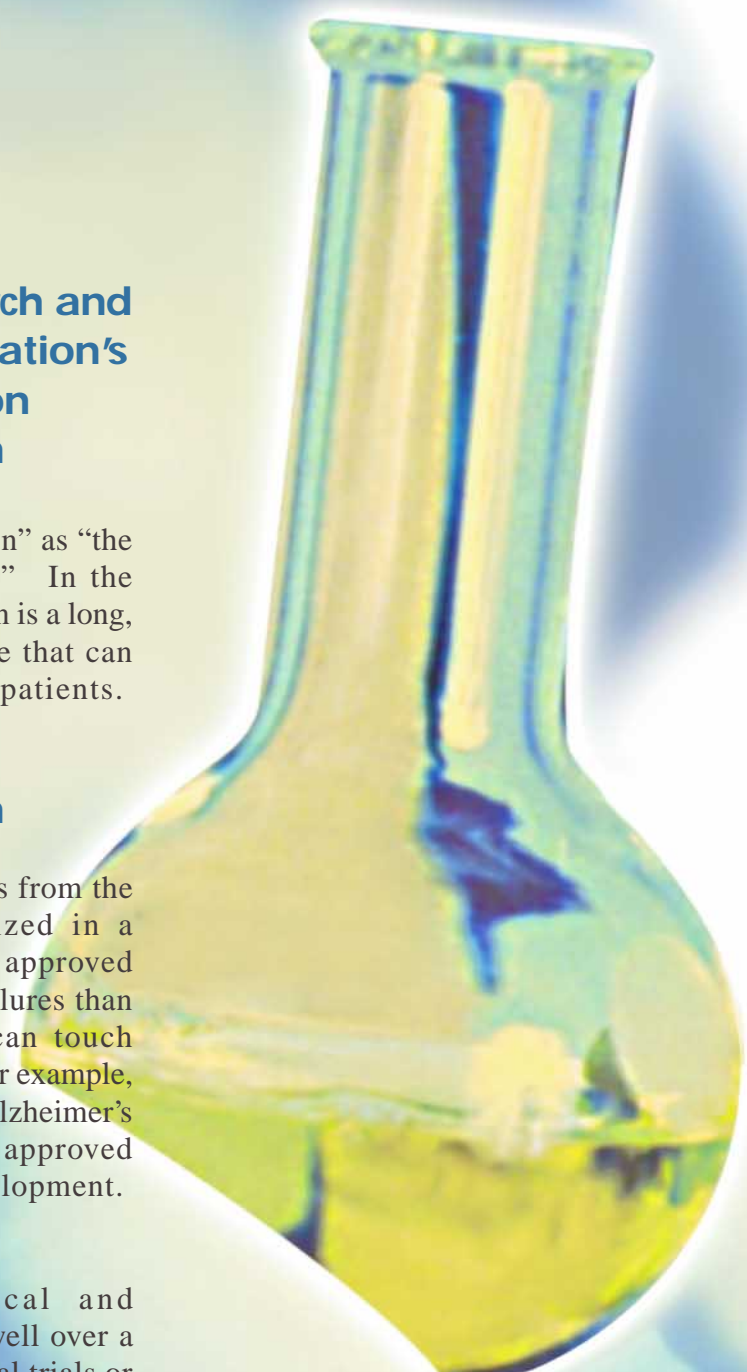
All together, pharmaceutical and biotechnology companies have well over a thousand new medicines in clinical trials or awaiting approval by the Food and Drug Administration (FDA). With more than 50,000 researchers working in America's pharmaceutical companies, the future of pharmaceutical innovation has never been brighter.

### Here is a highlight of some of the research and development underway:

According to a PhRMA survey published in October 2002, companies are testing 371

biotechnology medicines for nearly 200 diseases. Nearly half of these medicines target cancer, and many of them use cutting-edge technologies. For example, a medicine in development for non-small-cell lung cancer blocks the signaling pathway that enables tumors to grow. And a potential treatment for prostate cancer uses the patient's own blood to grow T-cells and activate the immune system to fight the disease.

A survey of medicines in development for older Americans found more than 800 medicines in testing for diseases of aging, including 30 for diabetes, 20 for osteoporosis



and 14 for Parkinson's disease. For example, one company is working on an inhaled form of insulin, which would greatly improve the quality of life for people with diabetes.

Another survey found nearly 200 medicines in the pipeline to meet the special needs of children. These include medicines for AIDS, asthma, cancer, cystic fibrosis, epilepsy, juvenile rheumatoid arthritis and other diseases. One of the medicines awaiting approval by the Food and Drug Administration is a monoclonal antibody to fight asthma. A monoclonal antibody is a laboratory-made version of the naturally occurring protein that binds to and neutralizes foreign invaders. In

clinical trials, the medicine sharply reduced asthma attacks in both adults and children.

## Dose of Hope

These cutting-edge medicines in development are the result of new knowledge about disease and the pharmaceutical industry's commitment to research and development. Last year alone, PhRMA member companies invested more than \$30 billion to research and develop new medicines. This innovation provides a large dose of hope for improved cures and better treatments for some of the most challenging diseases.

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