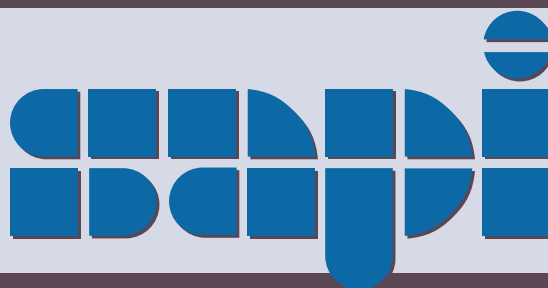


May 2001



NEWS

Newsletter of Singapore Association of Pharmaceutical Industries

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FOCUS ON

R & D

Encouraging New Clinical Drug Development The Role of Data Exclusivity

The role of data Exclusivity

The discovery of a pharmaceutical product is just the beginning of a complex puzzle in drug discovery and marketing.

To prove a product's efficacy and safety for its intended therapeutic use, it is necessary for the originator of the drug to conduct extensive testing on animals and humans in pre-clinical and clinical trials. Furthermore, tests need to be done in areas of toxicology, manufacturing feasibility and other scientific studies.

The results of these tests and studies, which are proprietary, are contained in registration dossier that is submitted to governmental authorities to obtain marketing approval for the product.

What is Data Exclusivity?

Data exclusivity or exclusivity of registration data is the period of non-reliance and non-disclosure that a government must provide to pharmaceutical registration data. Pharmaceutical registration data are the propriety data generated by scientific research conducted to demonstrate the efficacy and safety of new medicines and submitted to regulatory authorities for marketing approval.

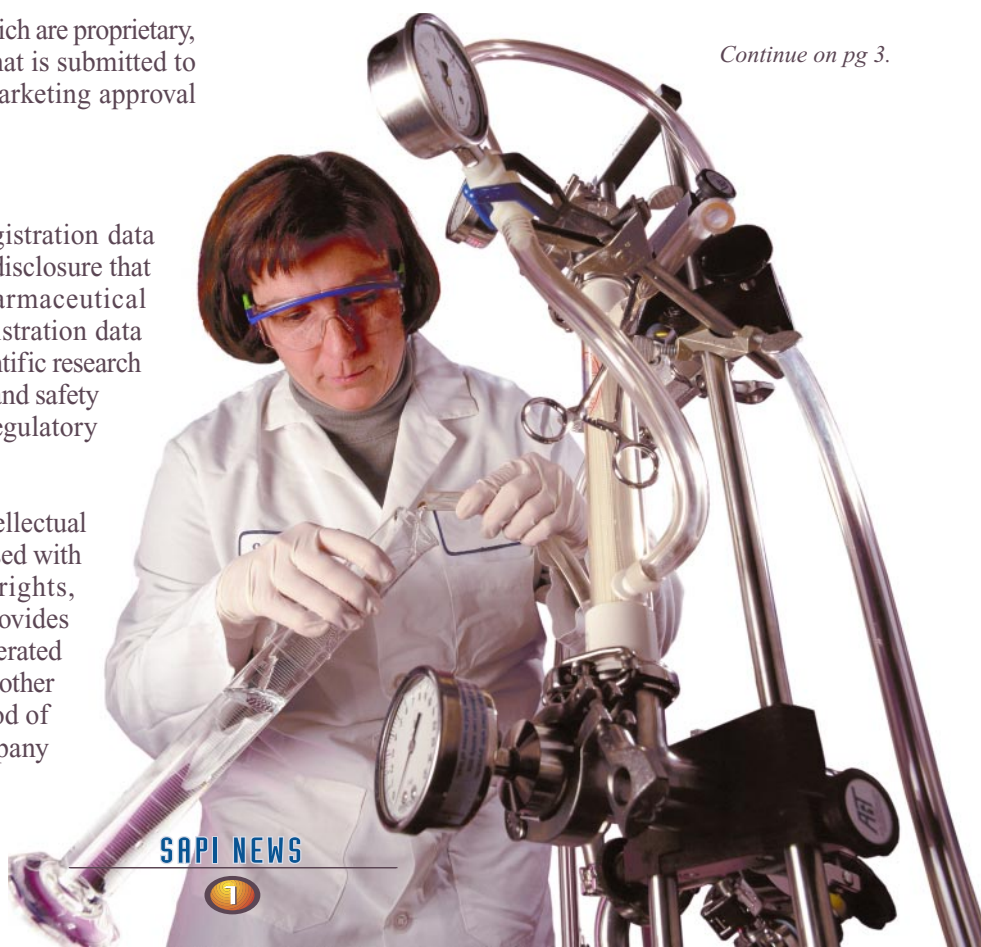
Data exclusivity is an independent intellectual property right and should not be confused with the protection provided by other rights, especially patents. Data exclusivity provides the holder with rights that the data generated by the holder may not be referred by another person or company for a specific period of time. It does not prevent another company from generating the data.

Why is it important?

Independent studies have shown that the entire drug development process from discovery to launch takes an average of 10 years and costs an average of US\$500 million. This involves considerable amount of time and expense.

The Agreement on Trade-Related Intellectual Property Rights (the 'TRIPs Agreement') specifically recognises the 'protection of undisclosed information' as being a category of intellectual property subject to protection.

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SAPI NEWS

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President's Message

S A P I

A Year with Many Changes in the Environment

Jimmy Chan, President of SAPI, comments on the current term

The past term has been a very interesting year. Many changes occurred in the healthcare environment. The coming year will be just as interesting as many of the initiatives of the government are implemented.

Looking at the External Environment

In April 2001, the Health Sciences Authority was officially launched. The formation of HSA marks a significant milestone in the development of the medical, pharmaceutical and scientific expertise in Health Sciences for Singapore.

In an effort to ensure affordable quality healthcare, a multi-disciplinary committee has been set up by the Ministry of Health to recommend policies, practices and processes. We are pleased that the Ministry of Health will continue to have regular dialogues with the pharmaceutical industry in a matter that goes to the core of people's concerns.

In the recent months, there have been many debates about the price of pharmaceuticals in Singapore. As more and more Singaporeans become more net-savvy and achieve higher education, we expect people to be increasing their usage of new innovative medicines.

Independent studies have shown that the pharmaceutical industry spends about US\$500 million to bring a product from the laboratory to the market. The market structure should encourage competition and reward innovation accordingly.

With the recent set-up of the Clinical Trials Coordinating Committee (CTCC), the Ministry of Health has proven that research and development is important. For members of SAPI, Research and Development is our lifeline and answer many of mankind affliction.

What Have We Done in SAPI?

With the numerous changes in the healthcare environment, SAPI has had the opportunity to be involved in strategic discussions with some of the groups involved.

SAPI is represented in the Information Communications committee, set up by the Ministry of Health. We believe that the Internet and e-commerce will assist in the efficiency of the healthcare management. SAPI is making recommendations through this committee in the areas of product advertising, procurement and information provision.

SAPI is working with the CTCC in its move towards encouraging more clinical trials to be conducted in Singapore.

The Board of Directors of SAPI has had the opportunity to meet with Dr. Clarence Tan, CEO of HSA, Dr. John Lim, Director of Centre for Pharmaceutical Administration, and Prof. Vivian Balakrishnan, CEO of Singapore General Hospital.

Various committees of SAPI have also had the opportunity to meet with the stakeholders of specific projects and policies.

SAPI acted as a liaison between the pharmaceutical companies and the Singapore National Heart Association with the release of the Hypertension Guidelines.

SAPI has updated its website to include more information. We are also planning to include other software to make the website more robust for members.

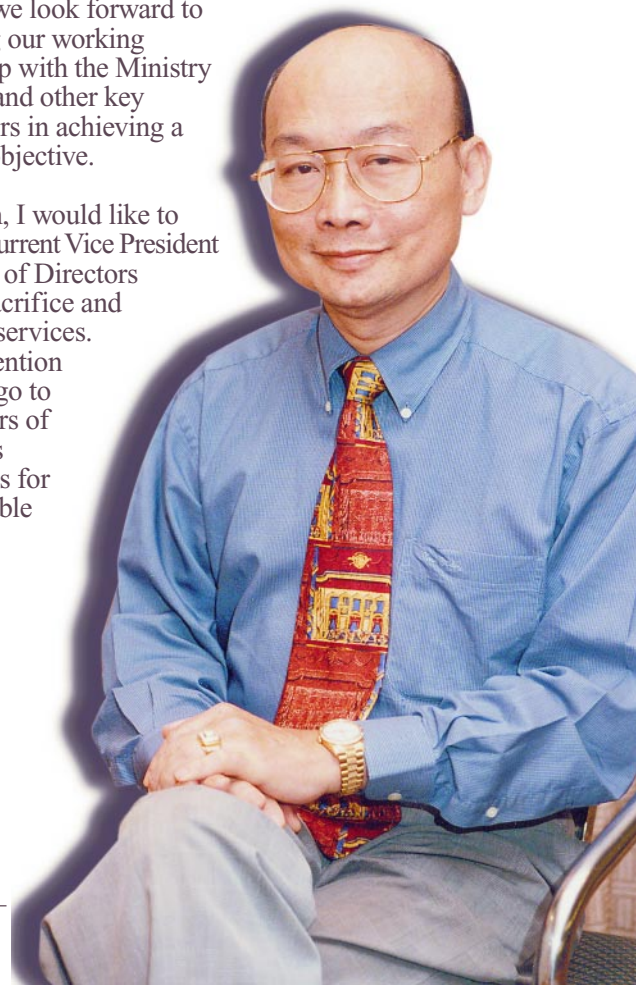
SAPI worked with the National Council of Social Service to raise funds during the Annual Dinner and Dance.

What's Next?

The coming term will be challenging. The various initiatives of the Ministry of Health will be implemented fully and dialogue will continue.

At SAPI, we look forward to continuing our working relationship with the Ministry of Health and other key stakeholders in achieving a common objective.

In addition, I would like to thank the current Vice President and Board of Directors for their sacrifice and dedicated services. Special mention must also go to all members of the various committees for their valuable services.



Governments are encouraged to protect the confidentiality of these data against its unauthorised use or disclosure to protect the proprietary interests of scientists and others, and to maintain the economic incentives for future pharmaceutical research and development.

The fact that both patent protection and data exclusivity provide incentives reflects the dual nature of the drug development process.

- Without the period of market exclusivity provided by the patent, research-based industry would not have any incentive to undertake the research leading up to the discovery of the innovative drug therapy.
- Without data exclusivity, the originators of the innovative drug would be placed at an unfair commercial disadvantage when compared to their generic competitors, who do not face similar costs of meeting the mandatory requirements set by regulatory bodies for product approval.

What is the current practice in the US and EU?

The EU and United States have acknowledged the right of data protection for a certain fixed period of time. After

the period has expired, reference to the data is permitted by generic companies. This protects the investments of the originator, as well as prevents unnecessary repetitive tests and trials.

In the EU, products that are approved through the centralised procedure have a 10-year period of data exclusivity.

In the United States, abbreviated applications for regulatory approval by subsequent applicants cannot be filed for five years after the originator's approval.

What needs to be done?

The pharmaceutical industry is required to provide registration data to governments to receive marketing approval. Pharmaceutical industries need the assurance that their extensive efforts to research, develop and bring new innovative products to market will not be subjected to unfair commercial use. With a clear understanding of the data exclusivity issues and a concerted effort by governments, this will be achieved.

Doctors are Surfing too!

SAPI

Singapore Doctors Clicking Their Way into Patient's Good books

Findings from a recent survey done among doctors in Singapore

Physicians in some Asean countries may be a tad upset at the rhetoric that - "The average Singaporean doctor could just be more net-savvy than their neighbouring counterparts!"

With 90% of the country's doctors using the net frequently, it may appear that Singaporean doctors, in comparison to those in other Asean countries, are much more infected with the web-surfing syndrome.

"I surf every day, since I have a computer at the clinic and one at home," Dr. Frankie Ng stated, adding that he personally still finds it a necessity in his work and daily life. "With Darwin's evolution theory being vindicated and this pendulous genetic engineering concept gaining momentum, the Internet is the easiest



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"I surf every day, since I have a computer at the clinic and one at home," Dr. Frankie Ng stated, adding that he personally still finds it a necessity in his work and daily life. "With Darwin's evolution theory being vindicated and this pendulous genetic engineering concept gaining momentum, the Internet is the easiest way for us to keep abreast with these developments" says Dr Ng. Another physician, Dr. Kenneth Leow, owner of a 24-hour clinic, shares similar sentiments although he claims to being only a modest surfer, frequenting it on alternate days rather than on a daily basis.

Some of their pet peeves

Singaporean doctors are particular that the information obtained is extensive, up-to-date and relevant to the region or country. Dr. Nirmala Nair who provides locum services in a clinic in her neighbourhood, religiously surfs the net at least 5 times a week, usually at a two-hour stretch. "I find that many sites promise exhaustive content, but do not deliver. They begin with a big bang and then fizzle out! The information is not frequently updated and contents are not as comprehensive as they should be."

On a similar note, Dr. Soh Lye Eng remarked, "Finding a comprehensive site that is relevant to Singapore is the surfer's biggest challenge. Many of the better sites are either US or Europe focussed."

Other frequent surfers like Dr. George Lam Sin Fook commented on hyperlinks that sometimes provide information that is unsatisfactory or redundant. He said, "This is frustrating and such a waste of precious time, especially with our ever-tight schedules".

Are all doctors net savvy?

While the majority of the country's doctors do boast of regular Internet usage, not all are net-savvy enough to approve or disapprove of the labyrinth of options on the net. Some doctors claim that their Internet usage is restricted to e-mailing alone. One such doctor is Dr. Phyllis Phang, a 52-year-old practitioner who claims

she already has all the paper references she needs for her work and obtains general information updates from the printed media.

Another doctor sharing this view is Dr. Adam Adnan who believes that the multitude of websites do not make surfing an easy task when carrying out specific searches for information under strict time constraints. "I barely have the time to refer to the net, especially if I am expecting a patient to walk in at any moment or if I have someone in the waiting room," he commented. He prefers waiting till the end of the day to catch up on the day's news and other updates. "Once I'm home, it's CNN on television or the newspapers for updates. I use the Internet only for e-mailing! I very rarely look to the Internet for updates. The last I surfed the net was 4 months ago!" he laughed.

Why else do doctors go surfing?

Some doctors claim that the government of Singapore is indirectly responsible for the high Internet usage among doctors. This is because certain accredited courses taken on the net accumulate points towards their Continuing Medical Education.

But is it always the joys of learning and accumulating CME points that drive frequent surfing? Some feel that net-conversant patients are forcing doctors to beef up on their net-using skills to obtain information which is important in the medical field. "Patients sometimes come to me having surfed the net and found something that confuses or intrigues them. They are highly likely



to form a negative opinion of the doctor if he or she 'pleads ignorance!'" quipped Dr. Soh Lye Eng. "That is what creates an increasingly competitive "shape up or ship out" environment," he deduced.

SAPI and Its 8 Committees

S A P I

Focus on the Trade Committee

SAPI has eight working committees that assist its primary members and associate members with the specific roles that each committee plays. Each working committee of SAPI consists of a Chairperson, who will then co-opt other members into the committee during the term. The 8 committees are Ethics, Finance, Regulatory Affairs, Membership & Programmes, Consumer Health Care, Trade, Training and Publications, Public Relations & Education. The committee members are individuals who volunteer their time and efforts to serve the industry.

Focus on Trade

The main role of the Trade Committee is to look at pharmaceutical industry issues that are of relevance to the local trading, sales and marketing of products by pharmaceutical companies. Monthly meetings are held, during which the committee reviews various issues such as credit and return policies, government healthcare policies and procurement policies with the aim of harmonising the terms within the pharmaceutical industry.

About the Trade Committee

The Trade Committee, together with SAPI also plays a pivotal role in maintaining or initialising contacts with relevant authorities to discuss industry issues, if necessary. These authorities include the Singapore Medical Association (SMA), Centre for Pharmaceutical Administration (CPA) and Pharmaceutical Society of Singapore (PSS). Thus the Trade Committee serves as an important platform where industry issues can be put forward, discussed and harmonised in a constructive and ethical manner.

The present Trade Committee for 2001 consists of 10 members from various pharmaceutical companies, including one representative from SAPI. Some of the issues being discussed at present are procurement of drugs via the Internet, e-commerce and its implications on the industry as well as the recent clustering of restructured hospitals.

Who Heads the Trade Committee?

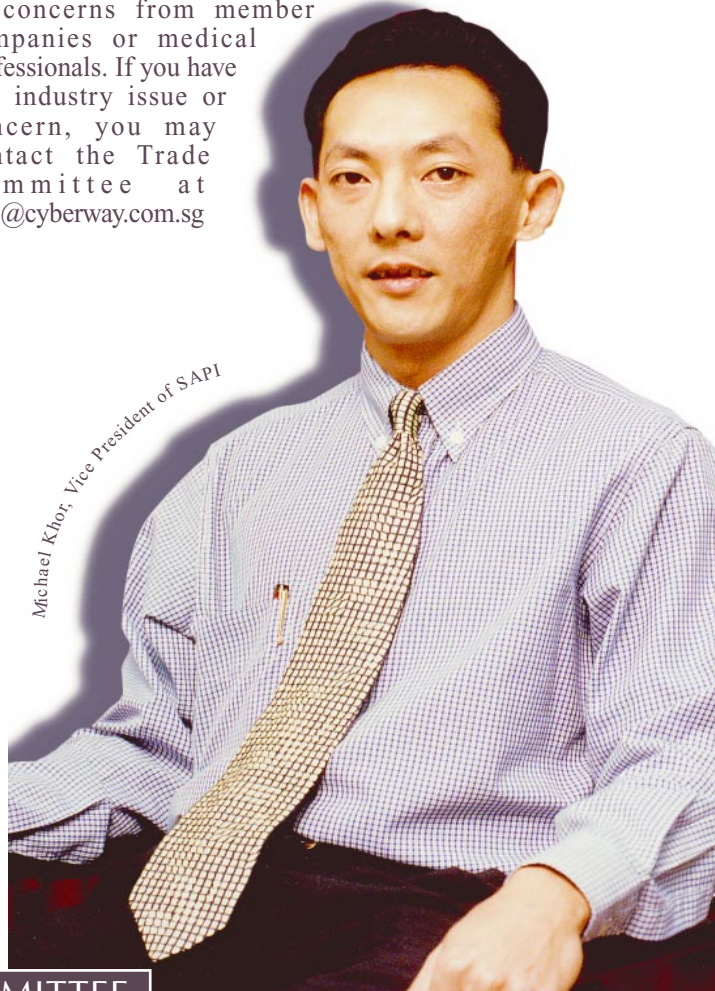
The current chairman of the Trade Committee is Mr. Michael Khor, Vice President of SAPI. "The Trade Committee is committed to bringing forth concerns faced by SAPI's members," Said Mr. Michael Khor.

"Of great interest currently is the healthcare restructuring," he added. The Trade Committee is monitoring the healthcare environment, and evaluating its impact for all parties involved. "We meet once every month to discuss issues and how we can overcome them," said Mr. Eric Ng, committee member of the Trade Committee.

But it is not all work. The members interact and get to know others when working together.

How Can You Reach the Trade Committee?

The Trade Committee welcomes volunteers, contributions or concerns from member companies or medical professionals. If you have any industry issue or concern, you may contact the Trade Committee at sapi@cyberway.com.sg



Michael Khor, Vice President of SAPI

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