Official Opening

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ON BEHALF OF THE HONORABLE MINISTER OF HEALTH, MALAYSIA

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In close cooperation with the Ministry of Health of Malaysia

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Salutations

Good morning.

I would like to first of all welcome all of you to the 5th International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Asian Regulatory Conference 2008 and would like to take this opportunity to say "Selamat Datang ke Malaysia" which means welcome to Malaysia to all our foreign delegates. It gives me great pleasure to officiate this conference especially since research and drug regulatory issues are subjects which are close to my heart.

I am delighted that the International Federation of Pharmaceutical Manufacturers & Associations chose to hold this conference here in Kuala Lumpur. I understand that participants have come from almost all countries in Asia and I hope that you will enjoy not only this meeting but also the variety of attractions which Malaysia has to offer our guests. To the distinguished panel of speakers representing the various drug regulatory agencies from Asia, Europe and USA, the pharmaceutical industry and WHO, I express my gratitude for your contributions in making this conference a reality.

I strongly advocate the fostering of close cooperation between the pharmaceutical industry and the regulators. I hope that all participants will take this opportunity to establish networking and build bridges rather than barriers in order to establish a common goal which is "improved healthcare for all".

Ladies and Gentlemen,

Medicines have become a very important & powerful tool, now more than ever, in improving the health status of populations and, in the long term, for reducing healthcare costs. As a practicing clinician, I am very aware of the fact that an ever increasing number of diseases are successfully managed today with drug therapy, especially with the availability of more effective, more reliable and more robust treatment options.

A study conducted by Dubois & Dean* and published in the 2006 Pharmaceutical Research and Manufacturers of America (PHRMA)

journal showed the evolution of clinical practice guidelines over the last 25 years to emphasize an increased role for drug therapies in health care. According to the study, factors which have contributed to this trend are:

- The rising burden of disease. More patients need treatment because of increased disease prevalence and lower thresholds for disease diagnosis and treatment. A good example of this is diabetes.

- An earlier role for the use of medicines. Medicines are now available to prevent disease and prevent complications, allowing patients to begin treatment at an earlier stage of disease development. This is exemplified by the use, at a much earlier stage in the disease process, of cholesterol lowering agents and antiplatelet drugs in patients at high risk for ischaemic heart disease when compared to the practice a few years ago.

- More multiple-medicine and extended-use regimens. Many treatment regimens now consist of combination therapies for a single disease condition and are often prescribed for extended maintenance use rather than for brief, acute care. For example management of asthma has changed from intermittent treatment of acute “attacks” to daily long-term management.

*(*R. W. Dubois and B. Dean, Evolution of Medicines in Clinical Practice Guidelines: Why More People Use More Medicines (Washington DC: PhRMA, 2006)*

Another factor which has led to the greater use of medicines is the increasing number of chronic diseases involving the growing geriatric population. This is illustrated by the increased prevalence of chronic diseases, cancers and previously under diagnosed conditions such as Alzheimer’s disease.

Meeting the need for more effective drugs with better safety profiles is a challenge to scientists and the research-based pharmaceutical industry. Scientists are working hard to tackle complex diseases with new approaches. Over the past 10 years, expanding knowledge of

the human genome, insight into how diseases occur at the genetic and molecular levels and the impact of cutting edge new technologies have begun to change how medicines are discovered. New possibilities are opening up. Treatments based on an individual's genetic make-up show greater promise to improve health care. Physicians today, in many cases, do not have the ability to predict whether an individual patient will respond to a specific treatment or not. Similarly, they may not know, at the outset of treatment, the likelihood of the individual patients developing any adverse reactions. Of course there are instances where they do. For example, as a hepatologist, I know which patients with chronic hepatitis C are likely to respond to treatment with interferon and ribavirin combination therapy by looking at the viral load, the viral genotype and the response at a specific time period after initiating treatment. But then again, the individual patient may still spring some surprises now and then, thereby making it challenging for us to be absolutely sure as to the outcome of treatment and the incidence of adverse reactions.

Personalized medicine could help physicians tailor the use of medicines for an individual patient. We are already seeing the first examples of personalized medicine reaching patients. For example, studies have shown that trastuzumab is effective in patients with metastatic breast cancer whose tumors overexpress the HER2 protein. In the future, advances in knowledge at the molecular and genetic levels may hold even greater potential for personalization.

The research-based pharmaceutical industry plays a key role in fighting diseases and improving public health through the medicines it develops. Its key contribution to medical progress is to turn fundamental research findings into innovative treatments that are not only available but more importantly, accessible, to patients who need these medicines.

All of us are aware of the fact that developing a new drug is a long and costly affair while chances of successfully marketing a new drug is quite low. There are many estimates of the cost of developing a new drug and one of the most cited studies is from the Tufts Center for Drug Development which has estimated the average cost for developing a new drug at US$802 million in 2001 compared with a

mere US$54 million in 1976. The estimated cost of producing a biological product was US$1.2 billion in 2005.

Pharmaceutical research companies are said to have contributed US$55.2 billion for new drug research and development in 2006, with US$443 billion being invested by Pharmaceutical Research and Manufacturers of America member companies. Data available on new chemical and biological entities show the predominant position of the USA as the leading inventor of new molecules in the world. During the period between 2001-2005, 61 new chemical and biological entities were developed in USA compared with 51 in Europe, 23 in Japan and 14 from the rest of the world.

The pharmaceutical industry is the sector with the highest ratio of R&D investment to net sales world wide. High rates of innovation result from high rates of return on investment in R&D. This creates the incentives necessary to continue research. This also implies that R&D will typically flow to clinical areas characterized by relatively large markets, either in terms of numbers of patients, or purchasers willing to pay the price, that in the long run will cover the costs and risks of these investments. Smaller markets or markets which are unable to pay such prices will unfortunately rarely attract these investments. The estimated global pharmaceutical sales in 2006 were US$643 billion and of this 47.7% were in USA while 8.6% was in the combined region of Asia, Africa and Australia. This illustrates that the USA is not only the greatest innovator in the field of drug development but also provides the biggest market for the sale of drugs.
Today there is rapid growth in the research environment in emerging economies such as China and India. There is also an increasing shift of R&D sites from Europe to Asia because of lucrative incentives such as tax relief and pioneer status.

Ladies & Gentlemen,

In tandem with Vision 2020, whereby Malaysia aspires to become a developed nation by 2020, we have strived to put in place the pre-requisite of international standards and practices so that our country is able to compete in the global arena. In the health care sector, we have introduced measures & mechanisms to ensure that clinical

research projects or trials that are undertaken as well as the development of medicinal products comply with accepted global standards.

In recognition of the need to coordinate and facilitate improvements in the quality of health care research and development, I am indeed proud to have established the National Committee for Clinical Research in 2000. As an initial initiative, the Malaysian Guidelines for Good Clinical Practice (GCP) was developed and introduced. Today, all doctors in Malaysia who undertake to conduct clinical research must be certified to have training & certification in Good Clinical Practice to ensure the quality and acceptance of the research data. We will not allow those without approved GCP training to conduct any clinical trial in this country. Happily, to date, we have more than 800 registered clinical investigators throughout the country. The MOH will continue to actively promote clinical research in Malaysia. One of our major efforts towards this direction is by establishing the network of clinical research centres throughout the country as one stop centres to provide a single point of contact and facilitate the industry's access to investigators and patients for the purpose of contract research. We are also strengthening research governance and ethical oversight as well as collaborating an partnering with premier research institutions within and outside the country and forming what we call, co-operative clinical research groups which is a consortium of investigators from a common therapeutic area to enable large scale clinical trials in multi-centre settings and rapid accrual of patients.

Ladies and Gentleman,

We are cognizant of the fact that it is not easy for research work done in many countries to attain global acceptance as the data produced must be in compliance with Good Laboratory Practice (GLP). In view of this fact, Malaysia has taken steps to implement GLP guidelines, along with other initiatives, to ensure acceptance of research data. We hope that Malaysia will be recognized as a member of non-OECD countries adhering to the Mutual Acceptance Data (MAD) system, whereby test data generated in Malaysia will be accepted in all OECD countries. This will then enable companies gain better access to markets and business opportunities in the entire 30 OECD countries, which currently produce a combined 60 % of the world's good and

services. We are, of course, not just hoping but have in fact taken steps towards this direction and are confident of being accepted as a member very soon.

Ladies and Gentleman,

Given the challenges of innovation, we are aware of the fact that continued R&D progress requires robust support in the form of strong patent protection incentives and cooperative efforts from the government. Investors in the field of R&D do not look for the cheapest location, but for the country where their intellectual property (IP) enjoys the best protection, and where the environment is most conducive to the creation of new IP.

The relationship between intellectual property (IP) and the protection of public health has been a major issue of debate in several international forums, particularly at the World Trade Organization (WTO) and the World Health Organization (WHO). The debate centres on whether the intellectual property system provides enough incentives into research and development (R&D) of medicines for diseases that disproportionately affect developing countries and allows access to existing medicines. In this regard, WHO has undertaken a major project that is geared towards stimulating the innovations of drugs for neglected diseases. The IPR issues will be addressed in such a manner that will complement existing mechanisms without stifling innovation.

Another topic where there is heated debate is on the issue of Data Exclusivity which would provide protection of knowledge and data. In line with Malaysia's aspirations to be able to produce innovative products through the R&D efforts in biotechnology, a stand has been taken to allow Data Exclusivity. The details of how this is to be implemented is being fine tuned to ensure that while a conducive climate for research is created, it will not be done at the expense of accessibility to essential medicines by the population at large.

Ladies and gentlemen

Pharmaceutical research and development contribute a major part of the research necessary to move new science from the laboratory to

the bedside. Through industry efforts, many new drugs and devices have been developed and marketed. These drugs have led to striking declines in mortality from heart diseases and strokes, among others, over the past 40 years. As the prime and main provider of healthcare in this country, we believe that the pharmaceutical industry must continue to play their role as a valued partner in the health system.

I am happy to note that this conference covers a wide range of subjects which are very relevant to both regulators and industry in this region.

With that, I would like to wish you all a very fruitful and successful conference and to our foreign guests, a pleasant stay in Malaysia.

Thank you.