Press Release on Animal Testing and Compliance to Good Laboratory Practice (GLP) of Organisation for Economic Co-operation and Development (OECD)

The recent developments on animal testing and subsequent reports in the press have once again brought to the forefront a controversy that has great significance to all of us. The Ministry of Health Malaysia considers itself an important stakeholder in this issue on account of its involvement in registering new medicinal products that are used to treat diseases and promote wellness. As a component of drug development programme, all internationally accepted drug discovery models incorporate protocols that require pre-clinical testing involving the use of animals.

At the outset, the Ministry of Health wishes to make an important clarification that as part of its regulatory requirement for innovator medicinal products, it does require the innovator to undertake pre-clinical studies that involve the use of animals before these studies proceed to clinical phase involving human subjects. But these pre-clinical studies are essential studies that are governed by international norms. There are guidelines that stipulate strict conditions on the use of animals with utmost respect for their welfare.

The use of animals in studies and biomedical research is a broad issue but the ministry feels that there must be distinctions made when the studies adhere to ethical standards and they eventually contribute towards advancement in medicine. Biomedical research is essential to the health and well-being of our society as it searches for ways and means to heal living organisms such as humans and other animals. Advances in biomedical research over the years have dramatically improved the quality and prolonged the duration of life in both human beings and animals. This would not have been possible without the use of animals in research.

There are a number of reasons why animal studies are necessary in the context of drug development process. Animal studies provide an opportunity for certain amount of environmental and genetic manipulation that is rarely feasible in humans. The similarities between humans and animals in terms of their anatomy and physiological functions also provide valuable information to a researcher. In many cases, they are susceptible to the same diseases that affect humans, thus enabling a good understanding of various diseases. More importantly, it may not be necessary to test new treatments on humans if preliminary testing on animals shows that clinical use cannot be established. Apart from that, regulatory authorities throughout the world require certain amount of animal testing to screen new treatments for toxicity to establish the safety profile of an investigational drug so that human subjects are not unnecessarily exposed to danger when the investigation proceeds to clinical phase. Finally, animal studies provide unique insights into the pathophysiology and aetiology of diseases, and often reveal novel targets for directed treatments.

It has to be emphasized that drug research institutions and laboratories that are involved in drug discovery studies and experiments generally are required to follow existing guidelines on Good Laboratory Practice (GLP) that prescribes adequate safety measures for the animals used in the study. Failure to comply with these requirements may put the entire drug registration process in jeopardy and as such there is generally a very high level of compliance by these research institutions and laboratories. Most of the animal studies conducted will have to undergo Ethical Review Process at these research institutions to ensure the use of animals at the designated establishment is justified. The aims of this review process are also to provide independent advice on the experiments and standards of animal care and welfare and the ethical use of animals. Current GLP also underlines the deployment of 3Rs i.e., replacement, reduction and refinement of the use of animals in research. The ultimate aim of the 3Rs is to substitute a significant proportion of animal research by investigating the development of alternative techniques including *in vitro* and *in silico* (computer simulation) studies. However, it is unrealistic to expect this to be possible in every area of scientific research in the immediate future.

Ministry of Health is serious in ensuring that local institutions and laboratories that are involved in pre-clinical testing adhere to high GLP standards. Apart from ensuring that the animal studies are conducted with adequate safety measures, the ministry is also concerned that the data generated at these premises should be acceptable in other Drug Regulatory Agencies throughout the world. To help potential enterprises tap the opportunities in drug development research and at the same time ensure compliance to international standards, the Ministry of Health has embarked on an initiative to make Malaysia a member of Non-Organisation for Economic Co-operation and Development (OECD) countries that adhere to GLP standards. This move will enable our local institutions and laboratories 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.

Malaysia is now a Provisional Member to this OECD Mutual Acceptance Data system (MAD) of GLP since October 2008. The National Pharmaceutical Control Bureau of the Pharmaceutical Services Division, Ministry of Health Malaysia has been tasked with the establishment of a GLP Compliance Monitoring Programme and accordingly has been designated as the Compliance Monitoring Authority (CMA) for the pre-clinical safety testing of test items contained in pharmaceutical products, cosmetics products, veterinary drugs and food additives in the country.

This is only an initial step in the long process towards attainment of full membership during which time both the CMA and the research institutions will be subjected to inspections by the OECD inspectorate to evaluate the level of compliance and adherence to GLP principles. Therefore, research institutions and laboratories must play their role by taking steps to ensure that pre-clinical safety studies conducted in their premise are GLP compliant and are in accordance to OECD standards. If full compliance to GLP is demonstrated by CMA and research institutions in the country, Malaysia is likely to be accepted as a full member in the year 2012. This will finally pave

the way for pre-clinical safety data generated in Malaysia to be accepted by all OECD countries and other adhering economies.

The Ministry of Health takes serious view of public concern on the use of animals in science, and is committed to full adherence to GLP and will ensure the following:

- Research institutions and laboratories only use animal experiments when required by law or where no scientifically acceptable alternative is available
- All tests on animals must be carried out responsibly
- Strict rules must be put in place to ensure that the animal tests carried out are justified on scientific grounds and only the most appropriate animal species are used
- The researchers must use as few animals as possible to achieve reliable results and design experiments ensuring the least possible amount of pain and distress to the animals.

The Ministry of Health wishes to provide an assurance that it will strive to ensure all research facilities, both public and private within its jurisdiction and surveillance will conduct animal studies in a manner that is reasonably expected of them and in tandem with international standards and norms. Inevitably, outliers risk rejection of their hard earned research findings and data accumulated over a period of time resulting in loss of investment and effort.

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