PRESS RELEASE BY THE MINISTER OF HEALTH MALAYSIA IN CONJUNCTION WITH THE "PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S) SEMINAR 2010" ON THE 10TH NOVEMBER 2010 AT THE LE MERIDIEN HOTEL, KUALA LUMPUR.

REQUIREMENT OF BIOEQUIVALENCE STUDY (BE) FOR ALL GENERIC PRODUCTS

The Ministry of Health (MOH), Malaysia started registration of pharmaceutical products and licensing of manufacturers of pharmaceuticals in 1985, with the enforcement of the Control of Drugs and Cosmetics Regulations 1984 to ensure products marketed in the country are safe, efficacious and of quality. Since then, the local pharmaceutical industry has undergone huge transformation to upgrade their manufacturing facilities in accordance with Good Manufacturing Practice (GMP) requirements. Recognising that Malaysia has a licensing and a GMP inspection system well in place, the Pharmaceutical Inspection Co-operation Scheme (PIC/S) accepted the country as its 26th member in January 2002.

Within the last decade, the pharmaceutical product market has charted an average growth of 10-15% yearly. Presently, the pharmaceutical product manufacturers in Malaysia export their products to about 70 countries throughout the world. The export numbers are increasing by the year. Due to our strict regulatory surveillance system that complies with international standards and the industry's willingness to comply to these requirements, Malaysian pharmaceuticals are widely accepted and recognised for their quality by the importing countries.

Realising the importance of bioequivalence (BE) studies for generic pharmaceuticals marketed in the country, MOH through its regulatory body, the Drug Control Authority (DCA) had enforced the need for BE studies since the year 1999. BE study is the most appropriate method to prove that the effectiveness of a generic product is equivalent to the innovator drug.

BE studies should be performed in clinical research centres. There are currently six (6) BE centres in Malaysia, mostly located in universities. Presently, most BE studies

are conducted out of the country because the number of BE centres that meet the required standard is very limited.

In line with international practice, MOH will soon enforce the requirement of BE studies to be conducted in accordance with established standards. Therefore, all BE research centres must strive hard to strengthen their clinical and laboratory infrastructure to comply with these requirements. Cooperation of all parties involved in complying with stipulated standards is crucial to move the pharmaceutical industry up the value chain. The country needs more BE study centres as there is a great demand for generic pharmaceutical products at this time in line with the World Health Organisation (WHO) recommendations for the use of generic pharmaceutical products to increase affordability and accessibility.

The government will continue to assure the quality of pharmaceutical products marketed in the country. Although currently, requirements for BE studies are only enforced for products containing the selected 112 active ingredients, MOH will now enforce the requirement for BE studies for all generics by 2012.

Quality generics will boost the local pharmaceutical industry and increase export opportunities for local products. MOH is confident that the requirement of BE studies for all generic products will also spur the local BE centres to upgrade their facilities and system to be in line with international standards.

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