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MINISTRY OF HEALTH MALAYSIA AND STANDARDS MALAYSIA

THE ACCEPTANCE OF MALAYSIA AS NON-ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD) MEMBER ADHERING TO THE MUTUAL ACCEPTANCE OF DATA (MAD) IN THE ASSESSMENT OF CHEMICALS ON GOOD LABORATORY PRACTICE (GLP)

OECD is an inter-governmental organisation established in 1960. It consists of 34 industrialised countries including many EU member countries, some non-EU European countries, the North American Free Trade Area (NAFTA) countries and some Asia-Pacific countries.

Good Laboratory Practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

With the MAD system, the data generated in the testing of chemicals in an OECD Member and non-Member countries adhering to MAD system in accordance with OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of mankind and the environment. This collaboration saves governments and chemical producers around €150 million annually.

On 13 February 2008, the Cabinet has agreed for Malaysia to adopt the Organisation For Economic Cooperation And Development (OECD) Mutual Acceptance of Data (MAD) in the Assessment of Chemicals for non-OECD members on Good Laboratory Practice (GLP) based on the *1997 OECD Council Decisions on adherence of Non-member Countries to the Council Acts related to MAD*. Malaysia expressed the intention through a letter sent by Minister of Health to OECD on 17 April 2008. On 2 July 2008, OECD invited Malaysia to become a Provisional Member for 2-3 years and Malaysia accepted the invitation on 28 July 2008.

Due to the vast scope of GLP, using the *Blue Ocean Strategy* approaches, two (2) agencies have been appointed as the National GLP Compliance Monitoring Authorities. The National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia and Department of Standards Malaysia, Ministry of Science, Technology and Innovation (MOSTI) have officially been designated as the GLP Compliance Monitoring Authorities (CMAs) in Malaysia. The NPCB is responsible for areas relating to pharmaceuticals (including vaccines, natural products and biologicals), cosmetics, veterinary medical products and food additives while the

Department of Standards Malaysia is responsible for pesticides, feed additives, non-pharmaceutical biotechnology products and industrial chemicals.

To achieve the desired goals, concerted efforts were carried out including promoting awareness, upgrading capacity and strengthening capabilities among CMAs and Test Facilities. After all the hard work and the readiness in both CMAs and Test facilities, *Mutual Joint Visit* (MJV) was conducted on both NPCB and Jabatan Standard Malaysia on 14-19 November 2011. The MJV outcome was presented in the *GLP Working Group* meeting on 29-31 May 2012 in Paris. The decision from this meeting was forwarded to the *OECD Council Meeting* which sat on 13 February 2013. Final decision from the *OECD Council Meeting* agreed for Malaysia to be Non-OECD Member adhering to MAD system on GLP. OECD has officially invited Malaysia on 6 March 2013 to be a Non-OECD Member adhering to MAD system on GLP. Malaysia accepted the invitation from OECD and effective from **29 March 2013**, Malaysia is officially a full adherent to the OECD Council Acts related to MAD in the Assessment of Chemicals. At present 34 OECD Countries as well as Argentina, Brazil, India, Malaysia, Singapore and South Africa adhere to the system.

The acceptance of Malaysia as Non-OECD Member adhering to MAD system on GLP is a big achievement for the country. With the acceptance, Malaysia will benefit in many ways as follows:

a) International acceptance of non-clinical data developed in Malaysia
b) Trade facilitation by reducing marketing time for local manufactured products marketed internationally
c) Exemption of non-clinical research being repeated in OECD countries
d) Saving costs for development of product
e) Overcoming existing technical barriers
f) Increasing local and foreign investments in research and development of products involving pharmaceutical, biomedical, biotechnology, biochemical in Malaysia.
g) Making Malaysia a development and research hub for non-clinical research.

Others benefits to be gained by Malaysia includes:

a) Creation of a network of government and industry experts
b) Formation of a Forum whereby new policies can be developed towards harmonization
c) Development of technical instruments to improve the quality of chemical evaluations and regulations

d) Access to information and advice from countries with different policy experience
e) Harmonised classification and labelling systems for chemical products
f) Increased availability of safety data on high production volume chemicals

Malaysia's participation in this MAD system highlights the mutual benefit of the partnership between OECD countires and major emerging economics. Thus, will boost Malaysia's economy and place Malaysia as one of the non-clinical researches hub in Asia.

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