



**DIRECTIVE UNDER REGULATION 29
THE CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984**

DIRECTIVE OF DIRECTOR OF PHARMACEUTICAL SERVICES GLP- 2009 (1)

**APPOINTMENT OF NATIONAL PHARMACEUTICAL CONTROL BUREAU
(NPCB) AS MALAYSIAN COMPLIANCE MONITORING AUTHORITY FOR
MONITORING COMPLIANCE TO ORGANISATION FOR ECONOMIC CO-
OPERATION AND DEVELOPMENT (OECD) PRINCIPLES OF GOOD
LABORATORY PRACTICE (GLP)**

OBJECTIVE

1. To inform the appointment of National Pharmaceutical Control Bureau (NPCB) as Malaysian Compliance Monitoring Authority (CMA) for monitoring compliance to OECD Principles of Good Laboratory Practice to the non-clinical safety testing of test items contained in pharmaceutical products, cosmetic products, veterinary drugs and food additives. This directive is issued by the Director of Pharmaceutical Services under Regulation 29 of The Control of Drugs and Cosmetics Regulations 1984. The directive is also published in the official website www.bpfk.gov.my.

BACKGROUND

2. GLP is a quality system concerned with the organisational process and the conditions under which non-clinical health and environment safety studies are planned, performed, monitored, recorded, archived and reported.

3. The purpose of these Principles of GLP is to promote the development of quality data.

4. These Principles of GLP should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these items is to obtain data on their properties and/or their safety with respect to human health and/or the environment.

Non-clinical health and environmental safety studies covered by the Principles of GLP include work conducted in laboratory, greenhouses, and in the field.

5. The Malaysian Government through a Cabinet decision in February 2008 had agreed to appoint NPCB as Malaysian Compliance Monitoring Authority (CMA) for monitoring compliance to OECD Principles of Good Laboratory Practice to the non-clinical safety testing of test items contained in pharmaceutical products, cosmetic products, veterinary drugs and food additives. The Drug Control Authority in 214th Meeting in March 2009, had endorsed and agreed to enforce this decision in accordance

IMPLEMENTATION

3. The Directive is as follows:

3.1 NPCB is appointed as the Malaysian GLP CMA for monitoring compliance to OECD Principles of GLP to the non-clinical safety testing of test items contained in pharmaceutical products, cosmetics products, veterinary drugs and food additives.

3.2 The NPCB GLP Compliance Monitoring Programme is intended to ascertain whether Test Facilities have implemented requirements as described in the documents of OECD Series on Principles of GLP and Compliance Monitoring.

3.3 Test Facilities requesting for verification and certification of compliance to Principles GLP, and subsequent inclusion into the NPCB GLP Compliance Monitoring Programme need to make the relevant application to NPCB.

COMMENCEMENT

4. This Directive shall be effective on 1 June 2009



(EISAH BT A. RAHMAN)

Senior Director of Pharmaceutical Services
Ministry of Health Malaysia.

c.c:

Ketua Pengarah Jabatan Standard Malaysia

Pengarah Biro Pengawalan Farmaseutikal Kebangsaan, KKM

Pengarah, Bahagian Keselamatan dan Kualiti Makanan, KKM

Pengarah, Institut Penyelidikan Perubatan, KKM

Malaysian Organization of Pharmaceutical Industries (MOPI)

Pharmaceutical Association of Malaysia (PhAMA)

Malaysian Animal Health and Nutrition Industries Association (MAHNIA)

Cosmetic, Toiletry and Fragrance Association (CFTA)

Federation of Malaysian Manufacturers – Malaysian Cosmetics and Toiletries Industry Group (FMM-MCTIG)

Chinese Medicine Manufacturers Association of Malaysia

Federation of Chinese Physicians of Medicines Dealers Associations of Malaysia

Persatuan Pengeluar- Pengeluar Ubat Tradisional Melayu Malaysia (PURBATAMA)

Pertubuhan Tradisional India Malaysia (PEPTIM)

Persekutuan Perubatan Tradisional Melayu Malaysia