KKM-55/201/005/01 (/S)

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

DIRECTIVE OF DIRECTOR OF PHARMACEUTICAL SERVICES CT1- 2009

REQUIREMENT FOR REGISTRATION OF CLINICAL TRIALS WITH NATIONAL MEDICAL RESEARCH REGISTER (NMRR) FOR SPONSOR/APPLICANT/ INVESTIGATOR WHO APPLIES FOR CLINICAL TRIAL IMPORT LICENSE (CTIL) AND CLINICAL TRIAL EXEMPTION (CTX)

OBJECTIVE

1. The directive called the Requirement for Registration of Clinical Trials with National Medical Research Register (NMRR) for sponsor/applicant/investigator who applies for Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX) is issued by the Director of Pharmaceutical Services under regulation 29 The Control of Drugs and Cosmetics Regulations 1984 (Amendment) 2006 . The directive is also published in the official website of the National Pharmaceutical Control Bureau, Ministry of Health, Malaysia. www.bpfk.gov.my.

BACKGROUND

2. Registration of clinical trials is very much an international norm and is endorsed by both the International Committee of Medical Journal Editors (ICMJE) and the World Health Organization (WHO). This is to ensure transparency and to increase public trust and confidence in the conduct of medical research as well as to inform physicians and prospective volunteers about ongoing/future research in which they may wish to enroll.

3. National Medical Research Register (NMRR) is a registry that encompasses all research activities that involve Ministry of Health (MOH) personnel or that is conducted in MOH facility or funded by MOH research grant. Registration of all these medical researches have been made mandatory effective from 1 January 2008. The registration schemes enable MOH management to document the level of research activity in the MOH, and also to track the progress of the researches it has approved and/or provided support such as funding.

4. At the moment, data captured through the NMRR does not reflect the real number of clinical trials conducted in Malaysia because not all clinical trials that require CTIL and CTX are conducted in the MOH facilities.

5. This directive will facilitate the monitoring of clinical trial activity and also will give a better reflection of the number of clinical trials conducted in Malaysia.

IMPLEMENTATION

6. The directive regarding the Requirement for Registration of Clinical Trials with National Medical Research Register (NMRR) for applicant who applies for Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX) is as follows:

(1) All clinical trials that apply for Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX) must be registered with the National Medical Research Register (NMRR).

(2) Failure by the sponsor/applicant/investigator to register his/her clinical research with NMRR may result in delay/non-issuance of CTIL/CTX.

COMMENCEMENT

7. This directive shall come into operation on 1st January 2010.

"BERKHIDMAT UNTUK NEGARA"

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c.c Pengarah Biro Pengawalan Farmaseutikal Kebangsaan

Semua Pengarah Kesihatan Negeri

Semua Pengarah Pusat Penyelidikan Klinikal

Pharmaceutical Manufacturers Association of Malaysia (PhAMA)

Malaysian Organization of Pharmaceutical Industries (MOPI)

Semua Jawatankuasa Etika

Semua Dekan Fakulti Perubatan/Farmasi