Biro Pengawalan Farmaseutikal Kebangsaan
National Pharmaceutical Control Bureau
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Ruj. Kami : (11) dlm. BPFK/PPP/01/03 Jilid 1
Tarikh : 28 FEB 2011

SEMUA PEMEGANG PENDAFTARAN

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan/ Puan,

PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984 (PINDAAN 2006)
ARAHAN PENGARAH KANAN PERKHIDMATAN FARMASI BILANGAN 2 TAHUN 2011:
DIREKTIF PENGUATKUASAAN KEPERLUAN MELAKSANAKAN DATA EKSKLUSIVITI DI MALAYSIA

Adalah saya merujuk kepada Arahan Bilangan 2 tahun 2011 oleh Pengarah Kanan Perkhidmatan Farmasi.

2. Dimaklumkan bahawa Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia dalam Arahan Bilangan 2 Tahun 2011 telah mengarahkan penguatkuasaan keperluan data eksklusiviti di Malaysia seperti pada surat arahan Bil. (11) BPFK/PPP/01/03 Jilid 1.

3. Pihak pemegang pendaftaran adalah diarahkan untuk mematuhi keperluan tersebut.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

(**SELVARAJA SEERANGAM**)
Pengarah Regulatori Farmasi
Biro Pengawalan Farmaseutikal Kebangsaan
Kementerian Kesihatan Malaysia

s.k. Pengarah Amalan dan Perkembangan Farmasi, BPF
Pengarah Penguatkuasa Farmasi, BPF
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ARAHAN DI BAWAH PERATURAN 29 PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984

BILANGAN 2 TAHUN 2011

ARAHAN BAGI MELAKSANAKAN DATA EKSKLUSIVITI DI MALAYSIA

OBJECTIVE

1.1 The Directive on Data Exclusivity (DE) is issued by the Director of Pharmaceutical Services under regulation 29 of The Control of Drugs and Cosmetics Regulations 1984.

1.2 The Directive is to protect the undisclosed, unpublished and non-public domain pharmaceutical test data, the origination of which involves a considerable effort, submitted as required to the Director of Pharmaceutical Services for the purpose of scientific assessment in consideration of the:

(i) Quality, Safety and Efficacy of any new drug product containing a New Chemical Entity

(ii) Safety and Efficacy for a second indication of a registered drug product as a condition for

(a) registration of any new drug product containing a New Chemical Entity; or

(b) approval for a Second indication of a registered drug product.

APPLICATION AND DATE OF COMING INTO FORCE

2.1 This Directive is applicable to:-

(i) New drug product containing a New Chemical Entity; and

(ii) Second indication of a registered drug product

2.2 This directive shall come into force on 01 March 2011.

DEFINITIONS

3.1 New drug product containing any New Chemical Entity means a product that contains an active moiety that has not been registered in accordance with the provisions of the Control of Drugs and Cosmetics Regulations 1984.

3.2 An active moiety is defined as the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds) or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

3.3 Second indication for a registered drug product means a single or cluster of therapeutic indications applied subsequent to the first indication(s) approved at the point of registration of the product. The application for approval of the second indication contains reports of new clinical investigations other than bioavailability studies.

GRANT OF DATA EXCLUSIVITY

4.1 Any person may apply for Data Exclusivity. Such application shall be made upon submission of documents to the Director of Pharmaceutical Services for the:

(i) registration of a new drug product containing a New Chemical Entity; or

(ii) approval for Second indication of a registered drug product.

4.2 An application for Data Exclusivity shall only be considered if the application in Malaysia for:

(i) New drug product containing a New Chemical Entity is made within eighteen (18) months from the date the product is first registered or granted marketing authorisation; AND

granted Data Exclusivity / Test Data Protection in the country of origin or in any country, recognised and deemed appropriate by the Director of Pharmaceutical Services.

(ii) Second indication of a registered drug product is made within twelve (12) months from the date the second indication is approved; AND

granted Data Exclusivity / Test Data Protection in the country of origin or in any country, recognised and deemed appropriate by the Director of Pharmaceutical Services.

4.3 Before the Data Exclusivity is granted:

(i) *The applicant of a new drug product containing a New Chemical Entity shall provide to the Director of Pharmaceutical Services the undisclosed, unpublished and non-public domain pharmaceutical test data, the origination of which involves a considerable effort; OR*

(ii) *The applicant for a Second indication of a registered drug product shall provide to the Director of Pharmaceutical Services, the reports of new clinical investigations other than bioavailability studies, conducted in relation to the*

second indication and the origination of which has involved considerable effort.

4.4 *The Director of Pharmaceutical Services shall decide on whether the application will be granted the Data Exclusivity. The period of the Data Exclusivity granted shall be made on a case to case basis.*

4.5 *The period of the Data Exclusivity* ***shall not*** *be more than:*

(i) Five (5) years for a new drug product containing a New Chemical Entity; and

(ii) Three (3) years for a second indication of a registered drug product. The period of Data Exclusivity is for the data concerning the Second indication only.

4.6 *Calculation of the period of Data Exclusivity:*

(i) *For a new drug product containing a New Chemical Entity, the period of Data Exclusivity shall be calculated from the date the product is first registered or granted marketing authorisation AND granted Data Exclusivity / Test Data Protection in the country of origin or in any country recognised and deemed appropriate by the Director of Pharmaceutical Services.*

(ii) *For a Second indication of a registered drug product, the period of Data Exclusivity shall be calculated from the date the Second indication is first approved AND granted Data Exclusivity / Test Data Protection in the country of origin or in any country recognised and deemed appropriate by the Director of Pharmaceutical Services.*

4.7 *Consideration of other applications upon the grant of Data Exclusivity:*

For a registered new drug product containing a New Chemical Entity, registration of any other drug product where the active moiety is in all respect the same as the active moiety in the registered drug product which has been granted Data Exclusivity in Malaysia can be considered if:

(i) *The applicant provides undisclosed, unpublished and non-public domain pharmaceutical test data, the origination of which involves a considerable effort to demonstrate the Quality, Safety and Efficacy of the drug product submitted for registration; OR*

(ii) *The applicant has obtained consent in writing for right of reference or use of the test data from a person authorised by the owner of the registered new drug product containing a New Chemical Entity.*

NON-APPLICATION OF DATA EXCLUSIVITY

5. *Nothing in the Data Exclusivity shall:*

(i) *apply to situations where compulsory licenses have been issued or the implementation of any other measures consistent with the need to protect public health and ensure access to medicines for all; or*

(ii) *prevent the Government from taking any necessary action to protect public health, national security, non-commercial public use, national emergency, public health crisis or other extremely urgent circumstances declared by the government.*

APPEAL

6.1 Any person aggrieved by the decisions of the Director of Pharmaceutical Services may make a written appeal to the Minister within fourteen days from the date the decision is made known to him and any decision of the Minister made on an appeal shall be final.

6.2 A person making an appeal may submit any supporting data or documents to the Director of Pharmaceutical Services not later than –

(i) *120 days for application of new products containing any New Chemical Entity; or*

(ii) *90 days for the application for second indication of a registered drug product.*

KUATKUASA

7.1 Arahan ini berkuatkuasa **1 Mac 2011.**

'BERKHIDMAT UNTUK NEGARA'

DATO' EISAH A. RAHMAN
Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia

sk:

Pengarah Regulatori Farmasi
Pengarah Amalan Perkembangan Farmasi
Pengarah Penguatkuasa Farmasi