

APPENDIX 10

DATA EXCLUSIVITY

1. INTRODUCTION

Data exclusivity refers to protection of undisclosed, unpublished and non-public domain pharmaceutical test data, the origination of which involves considerable effort, submitted as required to the Director of Pharmaceutical Services for the purpose of scientific assessment in consideration of the:

- a) Quality, safety and efficacy of any new drug product containing a New Chemical Entity
- b) Safety and efficacy for a second indication of a registered drug product as a condition for registration of any new drug product containing a New Chemical Entity; or approval for a Second Indication of a registered drug product.

For information on the Register of Data Exclusivity Granted in Malaysia, refer to:

[Register of Data Exclusivity Granted in Malaysia \(New Drug\)](#) and [Register of Data Exclusivity Granted in Malaysia \(Second Indication\)](#)

2. HOW TO APPLY

An application for Data Exclusivity (DE) can be made via a Letter of Intent (LOI) in conjunction with the:

- a) Application for registration of a new drug product containing a New Chemical Entity; or
- b) Application for a Second Indication of a registered drug product.

The LOI shall be addressed and submitted manually to the Director of NPRA.

The application must comply with all terms and conditions stated in Directive No. 2, 2011: *Arahan Bagi Melaksanakan Data Eksklusiviti Di Malaysia*.

The following details are extracted from Directive No. 2, 2011 on Data Exclusivity (DE) issued by the Director of Pharmaceutical Services under Regulation 29, Control of Drugs and Cosmetics Regulations 1984, [Bil. \(11\) dlm. BPFK/PPP/01/03 Jld. 1](#) (28 February 2011).

3. APPLICABILITY AND DATE OF COMING INTO FORCE

Applicable to:

- i) New drug product containing a new chemical entity; and
- ii) Second indication of a registered drug product.

New drug product containing any new chemical entity means a product that contains an **¹active moiety** that has not been registered in accordance with the provisions of the CDCR 1984.

¹An 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 non-covalent derivative (such as a complex, chelate or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

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.

4. GRANT OF DATA EXCLUSIVITY

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

- a) Registration of a new drug product containing a new chemical entity; or
- b) Approval for second indication of a registered drug product.

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

- a) 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 authorization; AND

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

- b) 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, recognized and deemed appropriate by the Director of Pharmaceutical Services.

Before the Data Exclusivity is granted:

- a) 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
- b) 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.

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.

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

- a) Five (5) years for a new drug product containing a new chemical entity; and
- b) 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.

Calculation of the period of Data Exclusivity:

- a) 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 authorization AND granted Data Exclusivity/ Test Data Protection in the country of origin or in any country recognized and deemed appropriate by the Director of Pharmaceutical Services.
- b) 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 recognized and deemed appropriate by the Director of Pharmaceutical Services.

5. 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:

- a) 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 if the drug product submitted for registration; OR

- b) 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.

6. NON-APPLICATION OF DATA EXCLUSIVITY

Nothing in the Data Exclusivity shall:

- a) Apply to situations where compulsory licences 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
- b) 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.

7. APPEAL

Any person aggrieved by the decisions of the Director of Pharmaceutical Services may make a written appeal to the Minister within fourteen (14) days from the date the decision is made known to him and any decision of the Minister made on an appeal shall be final.

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

- a) 120 days for application of new drug products containing any new chemical entity;
or
- b) 90 days for the application for second indication of a registered drug product.

Please refer also to [Appendix 24: Appeal](#).