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ADVOCATES AND SOLICITORS

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THINGS TO KNOW ABOUT DATA EXCLUSIVITY IN MALAYSIA

- Data Exclusivity ('DE') is administered pursuant to the Directive: ARAHAN BAGI MELAKSANAKAN DATA EKSKLUSIVITI DI MALAYSIA; Bilangan 2 Tahun 2011 ('Directive') which came into force on 1 March 2011. The Directive can be seen in http://portal.bpfk.gov.my/images/reg-info/DataEx/Directive_on_DE.pdf.
- DE under the Directive applies to undisclosed, unpublished and non-public domain pharmaceutical test data relating to (i) new drug product containing a New Chemical Entity; and (ii) Second Indication of a registered drug product. Application for DE is to be made through the submission of the relevant documents required under the Directive to the Director of Pharmaceutical Services.
- The application for DE in relation to a new drug product containing a New Chemical Entity must be made within 18 months from the date the product is first registered or granted marketing authorisation; AND granted DE/Test Data Protection in the country of origin or in any country, recognized and deemed appropriate by the Director of Pharmaceutical Services.
- For Second Indication of a registered drug product, the application for DE must be made within 12 months from the date the second indication is approved; AND granted DE/Test Data Protection in the country of origin or in any country, recognized and deemed appropriate by the Director of Pharmaceutical Services.
- New drug product containing any New Chemical Entity is defined as 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. 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.
- Second Indication for a registered drug product is defined as a single or cluster of therapeutic indications applied subsequent to the first indication(s) approved at the point of registration of the product.
- The period of the DE shall not be more than:

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

  (ii) 3 years for a Second Indication of a registered drug product (the period of DE is for the data concerning the Second Indication only).

- Calculation of the period of DE:

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

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

(iii) As of 26 August 2015, DE registrations have been granted for 33 new drug products containing New Chemical Entities.[1] As of 4 February 2014, 5 DE registrations have been granted for Second Indications of registered drug products.[2]

[1] http://portal.bpfk.gov.my/images/reg-info/DataEx/DE-Table-Update_26-08-2015.pdf (accessed 2 December 2015)
[2] http://portal.bpfk.gov.my/images/reg-info/DataEx/Register-of-DE-for-AI-04-02-2014.pdf (accessed 2 December 2015)

TRANS-PACIFIC PARTNERSHIP AGREEMENT ('TPPA')

FACT SHEET – Data Exclusivity & Biologics

- The text of the TPPA has been made available to the public and can be accessed here: http://fta.miti.gov.my/index.php/pages/view/267. Article 18.50 of the TPPA deals with Protection of Undisclosed Test or Other Data while Article 18.52 deals with Biologics.
- Article 18.50.1 provides that if a Party (i.e. the State or separate customs territory for which the TPPA is in force[3]) requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar product on the basis of that information; or the marketing approval granted to the person that submitted such information, for at least 5 years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.
- If a Party permits, as a condition of granting marketing approval for a new pharmaceutical product, the submission of evidence of prior marketing approval of the product in another territory, that Party shall not permit third persons, without the consent of a person that previously submitted such information concerning the safety and efficacy of the product, to market a same or a similar product based on evidence relating to prior marketing approval in the other territory for at least 5 years from the date of marketing approval of the new pharmaceutical product in the territory of that Party.
- Article 18.50.1 shall apply, *mutatis mutandis*, for a period of at least 3 years with respect to new clinical information submitted as required in support of a marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration.
- Article 18.50.1 shall also apply, *mutatis mutandis*, for a new pharmaceutical product that is or contains a biologic for a period of at least 8 years from the date of first marketing approval of that product in that Party or alternatively, for a period of at least 5 years from the date of first marketing approval of that product in that Party, through other measures, and recognizing that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.
- The Ministry of International Trade and Industry ('MITI') has announced[4] that the Malaysian government has agreed to extend similar data protection to biologics products. However, the DE conditions for registration will have to be met. For example, the innovator has to apply for registration of pharmaceuticals in Malaysia within 18 months from the date the product obtained its first marketing approval in any other country. It is explained that this is to encourage pharmaceutical companies to market their new drugs early to Malaysia.
- It has also been disclosed that the Malaysian government will be choosing the alternative option of providing 5 years of data protection, along with other measures while recognizing market circumstances for biologics. Examples of such measures may include existing regulatory and patent approval for biologics and biosimilars.[5]

The TPPA is expected to be tabled and debated by the Malaysian Parliament in a special seating in January 2016.[6] The issue of extending data protection and its application to biologics products is expected to be widely discussed.

[3] Article 1.3 of the TPPA - General Definitions
[4] http://fta.miti.gov.my/index.php/pages/view/274 (accessed 3 December 2015)
[5] http://fta.miti.gov.my/index.php/pages/view/279 (accessed 3 December 2015)
[6] http://www.nst.com.my/news/2015/11/113768/special-dewan-sitting-tpp-expected-jan-26 (accessed 2 December 2015)