

Law Number (12) for the Year 2006
Amending some Provisions of Law No (7) for the year 2003
Pertaining to Trade Secrets

We, Hamad Bin Issa Al Khaleefa, the King of Bahrain,

And after reviewing the Constitution,

After reviewing the Legislative Decree No. (18) for the year 1997 pertaining to regulating the profession of Pharmacy and pharmaceutical centers;

And Law No. (7) for the year 2003 pertaining to Trade Secrets amended by Law No. (35) for the year 2005,

The Shura Council and the House of Representatives have approved the following law which we hereby ratify and promulgate:

Article (1)

Recitals of the last paragraph in Articles (1) and (2) of Law No. (7) for the year 2003 pertaining Trade Secrets, shall be replaced with the hereunder :

Article (1) last clause:

Within the course of implementing provisions of this law, the information stipulated in the features hereinabove are thereto regarded as trade secrets. It shall not be regarded a violation of this herein Law, if the competent administrative authority undertakes measures to disclose such information due to a compelling need to protect the public, or if the said competent authorities undertook the necessary measures to guarantee suspension of unfair commercial usage of such information.

Article (2)

a) All data or tests submitted to the competent administrative authority that are the result of considerable efforts with an aim of obtaining an official

approval for marketing pharmacological or agrichemical product in which new chemical components are used shall be considered trade secrets.

b) Pursuant to provisions of Articles 2 *bis* to 2 *bis* (**b**) of this herein Law, the competent administrative bodies shall be obliged not to disclose received data or tests of those mentioned in the previous Paragraph until same become no longer confidential.

Article (2)

The phrase: " the Minister competent of the Intellectual Property" shall be replaced with the phrase "The Minister of Trade" stipulated in Articles (5) and (8) of Law Number (7) for the year 2003 pertaining to trade secrets.

Article (3)

New articles should be added to Law number (7) for the Year 2003 pertaining Trade Secrets with the Numbers (2^{bis}) and (2 A ^{bis}) and (B ^{bis}) that recite as per hereunder:

(A) If any person submitted to the competent administrative authority for the purpose of obtaining a permission to market a pharmaceutical product-which encompasses a chemical compound previously permitted to market within another pharmaceutical product – new clinical information besides such data related to biological equipollence, it is not permitted to market a similar or identical product by any other person before the elapse of three years from the date of granting the marketing permit, based on the clinical information previously disclosed by the first person, or according to other evidences pertaining to the marketing permit based on such information without the written consent of the first person.

(B) If any person submitted to the competent administrative authority for the purpose of obtaining a permission to market a pharmaceutical product of the type prescribed in Paragraph (A) of this article not submitted by another person in another country in terms of evidences representing new clinical information contrary to the information related to biological equipollence, it is prohibited to allow marketing by any other person within three years of the date of granting the marketing permit in the Kingdom, to market a similar or identical product being marketed in another country according to the said clinical information or any other evidences related to granting a permit to market the product in another country based on such information without the written consent of the person concerned in the other country.

(C) For purposes of this Article, the new Pharmaceutical product is that which does not entail a chemical component that was permitted to market in the Kingdom by means of use within a pharmaceutical product. The agrichemical product also means the product which does not encompass a chemical agent that was permitted for use in the Kingdom in an agrichemical product.

Article (2) *bis* (A):

A) If any person submitted to the competent administrative authority for purposes of attaining a permission to market a new pharmaceutical product, or a new agricultural-chemical product the marketing of which was permitted in another country based on the evidences previously submitted by that person pertaining to the safety and the efficiency of that product, same body shall refrain from permitting the marketing of an identical or similar product to another person without the written approval of the first person for a period of five years as of the date of the permission to market the new pharmaceutical product in the Kingdom of Bahrain, and ten years as of the date of the permission to market the new agricultural-chemical product in the Kingdom.

B) If any person submitted to the competent administrative authority with a purpose of attaining a permission to market a new pharmaceutical product, or a new agricultural-chemical product the marketing of which was permitted in another country based on the evidences previously submitted by that person pertaining to the safety and the efficiency of that product, same body shall refrain from permitting the marketing of an identical or similar product to another person without the written approval of the first person for a period of five years as of the date of the permission to market the new pharmaceutical product in the Kingdom of Bahrain, and for ten years as of the date of the permission to market the new agricultural-chemical product in the Kingdom based on previous information submitted in another country pertaining to the safety or efficiency of the product or any other evidences related to allowing the marketing of the product in another country without the written consent of the said person in the other country.

(2) *bis* (B) :

a) If any person submitted to the competent administrative authority for purposes of attaining a permission to market a new use of an agricultural-chemical product which was previously permitted in the Kingdom, information pertaining to the safety or efficiency of the product, same authority shall refrain from permitting the marketing the new use by another

person without the written approval of the first person for a period of ten years as of the date of the permission to market the new usage without the written consent of the first person.

b) If any person submitted to the competent administrative authority, for purposes of attaining a permission to market a new use of an agricultural-chemical product which was previously permitted in the Kingdom, information pertaining a new use of an agricultural-chemical product which was permitted in the Kingdom, which was not submitted by any other person in another country pertaining to the safety and efficiency of that product, same authority shall refrain from permitting the marketing of an identical or similar product by another person for a period of ten years based on the submitted information on the safety and efficiency of the new use of the produce or on other evidences to market the use of that product in another country without the written approval of the first person.

Article (4)

Ministers shall, in accordance with the competency of each, implement provisions of this law, which shall come into force as of the consecutive date of publishing it in the Official Gazette.

King of the Kingdom of Bahrain
Hamad Bin Issa Al Khaleefa,

Issued in Refaa Palace

Date : 1st of Jumada al-Awal 1427 A.H

28th of May 2006