SUPREME DECREE Nº 002-2009-SA

Regulation of Legislative Decree 1072, Protection of undisclosed test data or other data of Pharmaceuticals Products.

Chapter I
General Dispositions

Article1.- This Supreme Decree regulates the procedure that the Sanitary Authority must apply to comply with Legislative Decree 1072.

Article 2.- With effects in this Regulation, the following terms should be understood as:

a. Sanitary Authority: the "*Dirección General de Medicamentos, Insumos y Drogas*" (DIGEMID) of the Ministry of Health.
b. Test data: the data generated through clinical tests in phase I, II, and III, done to establish the safety and efficacy of a pharmaceutical product for human use containing a new chemical entity.
c. Other data on safety and efficacy: the data generated through pre-clinical studies, pharmacological and toxicological, made to establish the safety and efficacy of a pharmaceutical product for human use containing a new chemical entity
d. Undisclosed: all of which has not been made known to the public, by any means, before the application for protection, so that a person has knowledge of them.
e. Law: Legislative Decree 1072.

Chapter II
The approval procedure for protection

Article 3.- When the Sanitary Authority demands as a condition for the sanitary register the remittance of undisclosed test data or other data on safety and efficacy, necessary to determine the safety and efficacy of a pharmaceutical product containing a new chemical entity, the protection of such data shall be invoked in the file of the sanitary register.

When the sanitary register is requested according to article 3.2 of the Law, the protection of undisclosed test data or other data on safety and efficacy shall be invoked in the file of the sanitary register.

Protection of undisclosed test data or other data on safety and efficacy shall be granted in accordance to the Law and this Regulation.

Article 4.- The protection foreseen in the preceding article shall be granted by the Sanitary Authority provided the applicant has not obtained a previous sanitary register in Peru on the same new chemical entity and that the generation of such undisclosed test data or other data on safety and efficacy, has involved considerable efforts.

Article 5.- For the effects of the protection of undisclosed test data or other data on safety and efficacy, the following must be enclosed, in the same filing request of sanitary register:

a. Sworn statement that the requesting party is the person that generated the undisclosed test data or other data on safety and efficacy, or has been authorized in writing to use such data by such person when the requesting party is a different person along with such written authorization;
b. In the case a product comes from a foreign country, proof of marketing approval granted in the foreign country where the sanitary register of the pharmaceutical product containing a new chemical entity was obtained for the first time, indicating the date and place of the marketing approval granted, if it be the case;

c. Sworn statement that the test data or other data on safety and efficacy, for which protection is requested, have not been disclosed;

d. Sworn statement indicating not having been sanctioned, according to a final judgment of the administrative or judicial authority, for conducts or practices clearly against free competition, if the sanction directly refers to the use of undisclosed test data or other undisclosed data on safety and efficacy.

Article 6.- The sanitary authority may not authorize a third party without authorization from the person who submitted the undisclosed test data or other data, its reliance on such, in order to obtain the sanitary register, according to the Law and this Regulation, of a product containing the same new chemical entity, during the term of protection of 5 years.

In the case of article 5.b of this Regulation, the obligation referred to in the first paragraph shall be maintained for a period of 5 years from the date of the first approval of the registry in high sanitary surveillance countries referred to in article 3 of the Law and the General Health Law and its regulation, provided that the sanitary registration is granted within six months of the filing with the Health Authority of the complete application file, otherwise, the period of protection will be of 5 years from the date on which the health registration was granted in Peru.

What is established in article 3.2 of the Law, shall be applicable, when the protection of undisclosed data or other data necessary to determine the safety or efficacy of a product, is invoked on the basis of the reliance on a marketing approval granted in countries of high sanitary surveillance.

The protection granted will be limited to the undisclosed test data or other undisclosed data on safety and efficacy, indicated in the sanitary register resolution.

Article 7.- Once the sanitary registration request where the protection for undisclosed test data and other undisclosed data on safety and efficacy, has been submitted, the sanitary authority shall order the publication of the following information in the Official Newspaper "*El Peruano*", for one time only and at the account and expense of the applicant within fifteen (15) days from the filing of the application:

a. the identity of the applicant;
b. the International Common Denomination of the new chemical entity;
c. the name of the pharmaceutical product, pharmaceutical form and concentration;
d. the pharmacological action.

Article 8.- During the thirty (30) working days following the publication, whoever has legitimate interest, can oppose the granting of the protection to the undisclosed test data and other undisclosed data on safety and efficacy.

Article 9.- The opposition document must have the following:

a. Identification of the person that files the opposition;
b. Identification of the file and date of publication of the application;
c. Reasons for the opposition, accompanied by corresponding evidentiary documents, if it be the case;
d. Formal requirements foreseen in article 113 of Law 27444, Law of the General Administrative Procedure.

Article 10.- Once the opposing document is admitted, the sanitary authority will inform of it to who invoked the protection. The applicant shall have fifteen (15) working days, counting from the date he was notified, if he or she choose to, to defend his or her argument. This term could be extended at the request of the party according to what is established in Law 27444.

Article 11.- Once the period mentioned in the preceding article has expired, the sanitary authority shall issue a Resolution with a decision on the filed opposition.

Article 12.- An appellation can be presented to the hierarchic superior against the mentioned Resolution. The filing of the appeal will not suspend the effects of the contested act. With the

corresponding decision the administrative proceeding is exhausted, in relation to the presented opposition.

Article 13.- The sanitary authority will issue a decision on the protection of undisclosed test data or other undisclosed data on safety and efficacy, together with the granting or denial of the sanitary register. This decision shall be susceptible to reconsideration or an appellation.

With the decision on the appellation, the administrative proceeding is exhausted. The presentation of the appeal will not suspend the effects of the contested act.

Chapter III
Non disclosure

Article 14.- Undisclosed data or other data on safety and efficacy referred to in the Law and this Regulation shall not be disclosed and will be protected against disclosure, except in the cases established in article 4.3 of the Law.

Article 15.- The Sanitary Authority shall have the obligation to maintain the confidentiality of the undisclosed test data or other undisclosed data on safety and efficacy, presented by the applicant in the file of sanitary registration of a pharmaceutical product that uses a new chemical entity.

Chapter IV
Exceptions and Limitations

Article 16.- The exercise of the rights granted by this Supreme Decree will be subject to the exceptions and limitations of article 4 of the Law.

Article 17.- In accordance with article 4.1 of the Law, the sanitary authority at national level, ex officio or at the request of a party can authorize one or more third parties, to use the protected undisclosed test data or other undisclosed data on safety and efficacy for reasons of public health, emergency situations, or extreme urgency.

Furthermore, the sanitary authority may authorize a third party to use or rely on such data in order to obtain a sanitary register in the cases in which a compulsory license has been granted, pursuant to article 40 of Legislative Decree 1075, Complementary dispositions to decision 486 by the Andean community commission that establishes the common regime on industrial property.

Such authorization shall terminate upon the ceasing of the public health, emergency situation, or extreme urgency situations or, at the conclusion of the compulsory license period.

The authorization referred to in the previous paragraphs, does not affect the validity of the protection of undisclosed test data or other undisclosed data on safety and efficacy granted in accordance to the Law and this Regulation.

Article 18.- The Sanitary Authority shall allow the use, by third parties, of the protected undisclosed test data or other data on safety and efficacy or reduce the term of protection of such data, when the judicial or administrative authority determines that as result of a judicial or administrative process, the holder of the protection has been involved in anticompetitive practices related to the products with undisclosed test data or other undisclosed data subject to protection.

Chapter V
Information generation for the approval of the marketing registry

Article 19.- A third party can make the necessary acts related to quality tests, the validation of the process for production and control of the product; among others needed to initiate the procedure for the request of the sanitary register of a pharmaceutical product which undisclosed test data or other undisclosed data on safety and efficacy are protected. In this case, the

sanitary register can only be granted once the protection period granted by the Law has expired.

Chapter VI
Cancellation of the protection

Article 20.- The protection of undisclosed test data or other undisclosed data on safety and efficacy can be cancelled at any time, ex officio or at the request of a party when it is determined, as a result of an administrative procedure, that the protection has been granted against the provisions of the Law and this Regulation.

Final Complementary Provisions

FIRST: This Regulation will enter into force on the date of the entry into force of Legislative Decree 1072.

SECOND: What is established herein is complemented with the other provisions that establish conditions for the sanitary register of pharmaceutical products in the country.