

Legislative Decree N° 1072

PROTECTION OF UNDISCLOSED TEST DATA OR OTHER UNDISCLOSED DATA RELATED TO PHARMACEUTICAL PRODUCTS

Article 1.- Protection of undisclosed test data or other undisclosed data

When the Sanitary Authority requires as a condition to obtain the sanitary registration of a pharmaceutical product that contains a new chemical entity, the submission of undisclosed test data or other undisclosed data necessary to determine the safety and efficiency of such product, the Sanitary Authority will protect such data against its disclosure when generating it has involved considerable efforts.

Article 2.- New chemical entity

A new chemical entity is understood as a biologically active fraction, responsible for the pharmacological or physiological action of an active principle, which at the moment of the Sanitary Registration request has not been included in sanitary registrations previously granted in the country.

Under no circumstance, will the New Chemical Entity be considered as:

1. Different therapeutic uses or indications from those authorized in other previous sanitary registrations of the same chemical entity or combinations of known chemical entities.
2. The changes in the way of administrating it, in the dosage ways, in the modifications in pharmacokinetics, in the dissolving time and in the bioavailability, authorized in other previous sanitary registrations of the same chemical entity.
3. The changes in pharmaceutical forms or in formulations of chemical entities already registered.
4. The salts (including salts with hydrogen bonds), esters, ethers, complexes, chelates, clathrates, isomers, metabolites, co-crystals, polyphorms, solvates, pure forms, particle sizes, prodrugs, or those chemical structures notwithstanding their forms, disposition or expression that are based on a previously registered chemical entity.
5. The combination of an already known chemical entity and a new one.

Article 3.- Use of the protection by third parties

No other person other than that whom submitted the undisclosed test data or other undisclosed data necessary to determine the safety and efficacy of a product may, without the authorization of such person, use such data to support an application for approval of a sanitary registration during the protection period normally of five years.

The Protection Period referred to in the previous paragraph will be counted from:

1. The date the sanitary registration was granted in the national territory; or,
2. The date of the first marketing approval, if the sanitary registration is based on a marketing approval granted in a country with high sanitary monitoring as provided in the Regulations of this law; and it is granted within six months after the submission of the complete application file.

In order to determine the protection period against the use by third parties of protected undisclosed test data or other undisclosed data related to safety and efficiency, the Health Authority will take into account the nature of the data and the efforts and expenses made to produce them.

(*) *Text as modified by the 5th Article of Law N° 29316, Publisher on January 14th, 2009.*

Article 4.- Exceptions and limits to the right of protection

1. Notwithstanding the provisions of this Law, the Sanitary Authority, ex officio or at the request of the party, in order to protect public health, may authorize one or more third parties to use or to be based on undisclosed test data or other undisclosed data submitted in the sanitary registration or in the sanitary registration granted by reference, taking into consideration the following:
 - a. The World Trade Organization Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2)(The "Declaration");
 - b. Any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration; and,
 - c. Any amendment of the TRIPS Agreement to implement the "Declaration".
2. Nothing provided in this Law will prevent a third party from requesting the sanitary registration of a pharmaceutical product, which has protected undisclosed test data or other protected undisclosed data, by using its own test data as evidence of the safety and efficiency of the product, independently from the data submitted by the other applicant during the protection period granted to the data of that other applicant; provided that the Sanitary Authority does not base its decision on the undisclosed test data or other undisclosed data previously protected; and
3. The Sanitary Authority may disclose the test data or other data, if it were necessary to protect public health, provided measures are taken to avoid its disloyal commercial use.
4. The exercise of the rights established in this Law, are subject to the Competition Laws of Peru.

() Text as modified by the 5th Article of Law N° 29316, Publisher on January 14th, 2009.*

Article 5.- The abbreviated procedure

Subject to what it is established in this Law, nothing will limit the application of abbreviated procedures for the sanitary registration of pharmaceutical products based on studies of bioequivalence or bioavailability. In this case, the sanitary registration will be provided once the period of protection, established in article 3 of this Law and its Regulations, has ended.

() Text as modified by the 5th Article of Law N° 29316, Publisher on January 14th, 2009.*

Article 6.- Expiration of the Protection

The protection established in this Law could be cancelled when as a result of an administrative or judicial procedure, it is determined that the protection has been granted contravening the provisions of this Law.

After the expiration of the protection period for the undisclosed test data or other undisclosed data, any person may base itself on such information in order to support their application for sanitary registration.

Article 7.- Administrative resources

Administrative acts susceptible of contradiction, issued under this law, can be subject to reconsideration or appealed before the correspondent competent area.

The use of the resource will not suspend the effects of the contested act.

Article 8.- Transparency measures

Information about the applicant's identity of the sanitary registration and about the pharmaceutical products for human use for which undisclosed test data and other undisclosed data are submitted will be published in the official newspaper "El Peruano" only once and at the expense of the requesting party, in order for third parties who consider their rights affected to submit their opposition, enclosing the corresponding information, within 30 working days following the publication of the application.

The Ministry of Health will publish in their website, with informative purposes, the applications for sanitary registration, indicating the identification of the applicant and the information regarding the product for which the application has been made.

In the same manner, the Ministry of Health will publish in their website the sanitary registries granted; indicating, when appropriate, if there is protection of undisclosed test data or other undisclosed data, the new chemical entity, and the dates of granting and expiration of the protection.

The publications referred to in the second and third paragraphs of this article will be done within the 2 working days after the date of presentation of the application or the granting of the sanitary registration, depending on which case applies.

() Text as modified by the 5th Article of Law N° 29316, Publisher on January 14th, 2009.*

FINAL COMPLEMENTARY DISPOSITIONS

FIRST: Entry into force

This Legislative Decree shall enter into force after the entry into force of the Trade Promotion Agreement signed between Peru and USA.

SECOND: Regulations

This Legislative Decree shall be regulated in a period not exceeding one hundred eighty (180) days after its publication in the Official Newspaper "El Peruano"

THIRD: Pharmaceutical products previously approved:

The provisions hereof shall not apply with respect to a pharmaceutical product containing a chemical entity that has already been adopted in Peru for use in a product, before its entry into force.