

DATA EXCLUSIVITY: Encouraging Development of New Medicines

JULY 2011



International
Federation of
Pharmaceutical
Manufacturers &
Associations

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Acknowledgements

Surveys of national laws on any subject are always a laborious task. The compilation of the individual country laws relating to the protection of registration data is made more complex because relevant provisions can be found in a country's patent laws, as well as in its regulatory or unfair competition laws. Further complicating this scenario is the fact that international treaties are self executing in certain countries.

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) would like to acknowledge the valuable contributions made by Carol Ann Williams of Pfizer, who worked diligently to collect and collate these laws, and to David Korn of PhRMA, for his valuable review of the final document.

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Introduction

The research and development process is characterized by a high degree of scientific, regulatory, and economic risk. Enormous quantities of time, effort, and money are invested in the research and development process to bring a new medicine to the market. Typically, discovering and developing a new medicine takes an average of 10-15 years, and for every 5,000-10,000 compounds investigated, only one is approved and marketed. The cost of developing a new medicine now totals on average more than USD 1.2 billion¹. These investments in R&D have no guarantee of a return, with statistically far more failures than successes in the laboratory.

The generation of pre-clinical and clinical trial data takes considerable time, effort and expense, and begins when a compound is identified as a potential medicinal product. Scientists and researchers may think that a compound has certain properties and will act in a certain manner, but to ascertain the underlying proof of concept, extensive testing is required. Authorities use these data to assess the product's quality, efficacy and safety before a medicinal product is approved for use in patients. Even after marketing, clinical studies and pharmacovigilance continue.

In this entire process, it is important to note that the innovator assumes the entire risk for the generation of the data. The innovator will not know in advance whether the data will demonstrate a safe and effective product and/or whether the regulatory authorities will consider the data sufficient to support the marketing of that product. If, at any stage of the development process, a test or clinical trial is unsuccessful, or if the authorities require further testing, the development process may be substantially delayed or stopped altogether.

Data exclusivity provides a limited duration of time during which only the owner or generator of this preclinical and clinical trial data can use it for purposes of marketing authorization, creating an important incentive for pharmaceutical companies to make the enormous R&D investments required. It helps to ensure a limited period during which an adequate return on that investment can be made by those few medicines that do make it through the R&D process and obtain market approval.

Patents are an important form of intellectual property, but are not themselves necessarily sufficient to create the favorable environment needed to support the development of medical advances. Data exclusivity is not an extension of patent rights, and it does not prevent the introduction of generic versions of the innovative drug during the data exclusivity period, as long as the marketing approval of the generic version does not use or rely upon the innovator's test data. Patents and data exclusivity are different concepts, protect different subject matter, arise from different efforts, and have different legal effects over different time periods.

The Role of Data Exclusivity in Economic Growth, Investments and Improvement of Health Care Systems

Data exclusivity can be a key consideration in the business decision to introduce new innovative drugs into a market. The incentive provided by exclusivity periods is well recognized, particularly for pediatric and orphan drugs. Exclusivity periods based on data developed in conjunction with study of these specific uses is a highly appropriate tool for providing the incentives to investigate previously "neglected diseases" areas.

In addition, when an innovative medicine is introduced into the national health care system, doctors, nurses, hospitals and pharmacies must be educated. This is usually done by the innovator having developed all the scientific information necessary for approval of the medicine. The innovator closely monitors reports on treatment results and ensures patient safety by incorporating data in its local product registration, launch and education program.

By providing a means for the innovator to potentially recoup the costs involved in conducting any locally required clinical tests for marketing approval and the significant costs of introducing a new product to the market, countries which offer data exclusivity are encouraging businesses to move their product, investment and potential manufacturing to their markets earlier. If other companies could immediately use these data to obtain their own marketing authorization, thus competing with the innovator, there would be less incentive for the innovator to invest in that market or to conduct the necessary trials.

¹ J.A. DiMasi & H.G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics* n. 28 (2007): 469-79.



Data exclusivity can also enhance technology transfer and can stimulate generic drug production or medicines for specific or unmet needs. By providing an incentive to introduce new innovative medicines to a market, data exclusivity can result in greater access to new innovative medicines and spur the introduction of generic medicines once the exclusivity period ends. Data exclusivity is a tool that recognizes and rewards the time, effort, and economic investments made by the innovator in order to bring a new medicine to market, while also providing a means to support greater access to those new medicines and over time, to generic medicines as well.

Data Exclusivity and the TRIPS Agreement

This concept of data exclusivity is embodied in Article 39.3 of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which most WTO Members committed to implement in their national legislation. TRIPS' Article 39.3 provides the following:

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

The requirement that WTO Members not rely on the originator's data for a specified period of time is reflected in the concept of "unfair commercial use". It is important to note however that even prior to the conclusion of the WTO TRIPS Agreement in 1994, some countries recognized the proprietary nature of registration data and enacted laws that precluded their regulatory authorities, for a fixed period of time, from relying on or otherwise using the data submitted by the originator for the approval of copies of the medicine without the permission of the originator.

Today, a number of countries maintain that the proprietary data that is provided to the Ministries of Health for obtaining registration of the innovator's products is protected under their unfair competition laws and that it is, consequently, not necessary for them to enact legislation that expressly implements TRIPS Article 39.3. As a general rule, such protection, which requires non-disclosure of information and puts the burden of enforcement on the owner of the proprietary information, is insufficient to meet the TRIPS Article 39.3 obligation.

Compilation of Laws

The following is a compilation of national laws relating to the protection of registration data in the WTO Members and candidates for accession to the WTO². For most countries, the texts of these laws, or their functional equivalents, are provided³. There are some countries, however, that simply provide de facto Article 39.3 protection because of the self-executing nature of their international agreements. There are other countries that have yet to provide any protection to the innovator's dossier and/or to enact any legislation.

For ease of reference, the countries are grouped by their geographic area and then listed alphabetically within that area. Care has been given to ensure the accuracy of these laws; however, the reader should check the actual text of a specific country's law before relying thereon, as some of these laws (and their effective dates) may change.

² The terms of protection are the general terms, under the current legislation in the jurisdiction, for data associated with so-called "new chemical entities." They do not systematically include terms under prior legislation, terms that are transitional, terms for data associated with new indications and formulations, terms for data associated with orphan drugs, or terms for data arising from pediatric studies. Unless otherwise stated, the terms are measured from the date of approval of the product associated with the data to the date when those relying on the data may enter the market. It should be noted, however, that some jurisdictions permit others to file applications in reliance on data associated with an approved product and will instead specify when such applications can be filed, sometimes in addition to when the product may enter the market.

³ The listing of a law or regulation in this publication should not be seen as implying that they comply with international obligations under TRIPS and/or other legal instruments.

Abbreviations

EC	European Community
EEC	European Economic Community
EMR	Electronic Medical Record
EU	European Union
FTA	Free Trade Agreement
KFDA	Korea Food & Drug Administration
NAFTA	North American Free Trade Agreement
TRIPS	Trade Related Aspects of Intellectual Property Rights
WTO	World Trade Organization

Antigua & Barbuda



Argentina



Bolivia



Brazil



Canada



Chile



Colombia



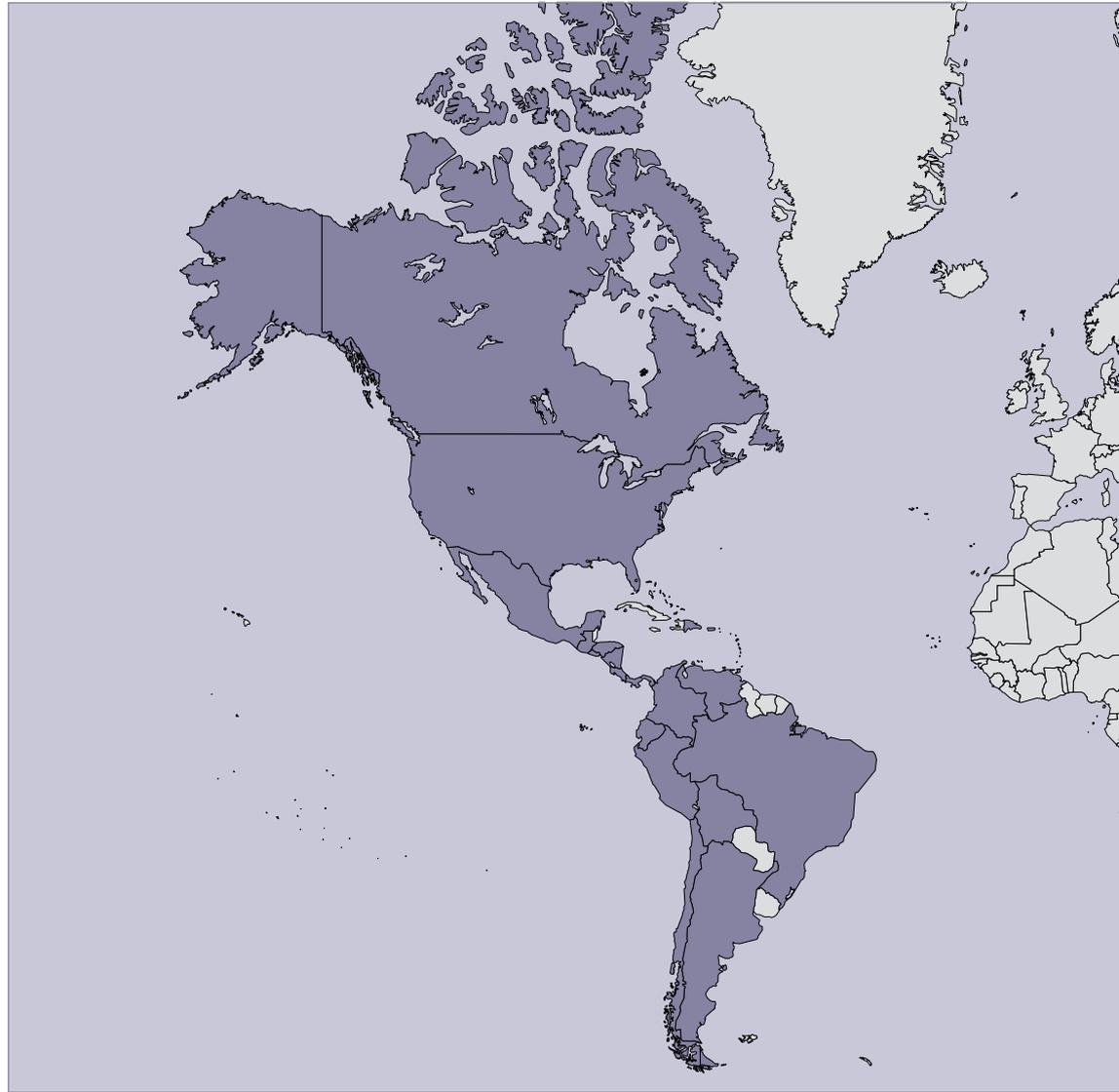
Costa Rica



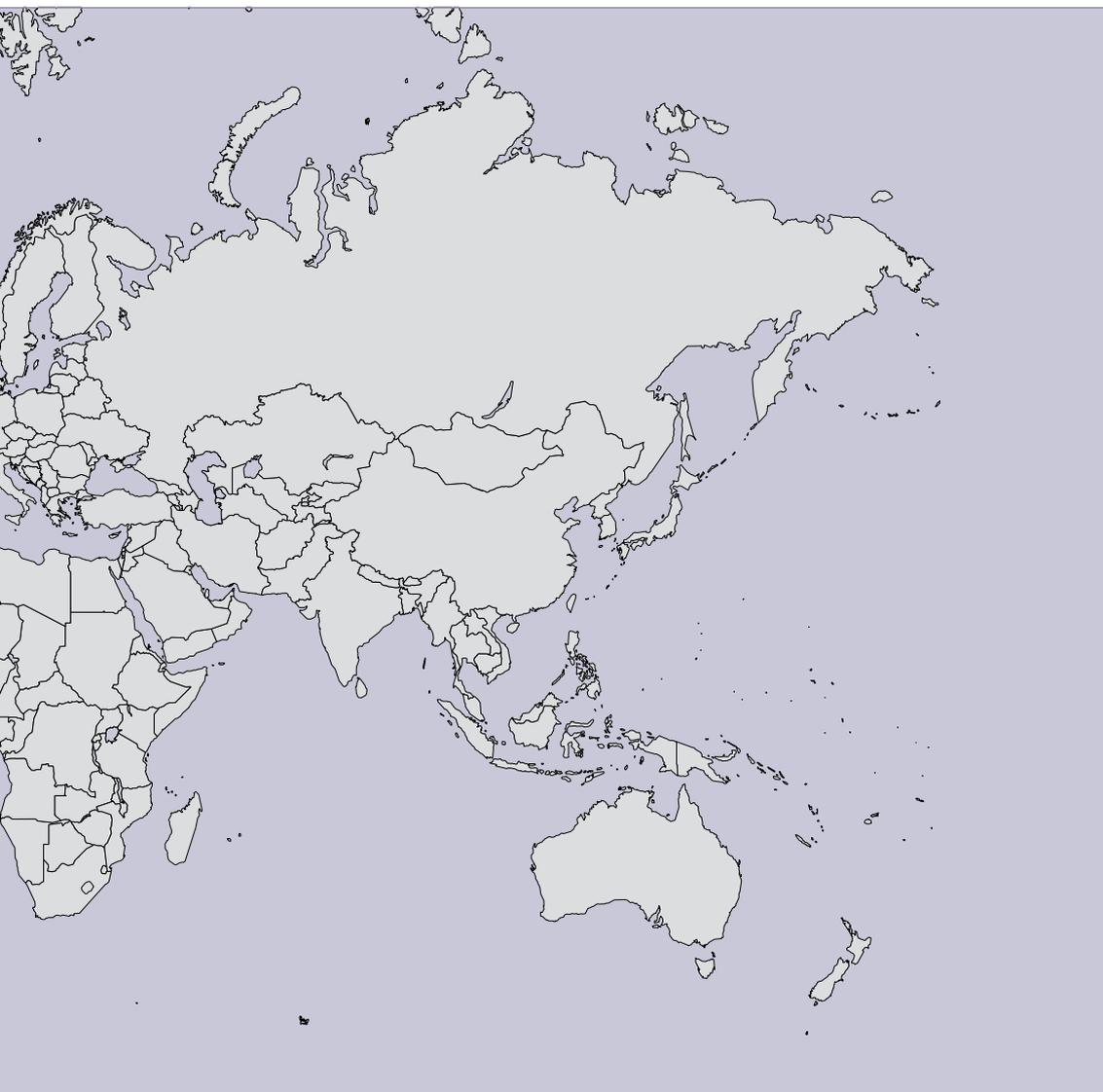
Dominican Republic



Ecuador



Americas



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Antigua & Barbuda



Protection Against Unfair Competition Act of 2006

Article 9(4)

- (4) Any act or practice, in the course of industrial or commercial activities, shall be considered an act of unfair competition if it consists or results in
 - (a) an unfair commercial use of secret test or other data, the origination of which involves considerable effort which have been submitted to a competent authority for the purpose of obtaining approval of the marketing of pharmaceutical or agricultural chemical products which utilize new chemical activities, or
 - (b) the disclosure of such data, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Antigua &
Barbuda
Not specified



Argentina

Law on the Confidentiality of Information and Products, No. 24,766, Articles 4 and 5

Article 4 – When requesting the approval for the registration or the authorization for marketing products involving new chemicals not previously registered in Argentina or in any other country, information on the effectiveness and safety of the product shall be provided to the local Public Health Authority. Inasmuch as this information meets the conditions listed in Article 1 and is the result of significant technical and economic effort, it will be protected from dishonest commercial use as defined by this law, and its disclosure will not be allowed.

Article 5 – In case of the products are registered or their marketing authorized in Argentina or in any of the countries listed in Addendum I – including the case described in the previous article once the registration of the product is completed in Argentina or in any of the countries listed in Addendum I – the local Public Health Authority will approve or authorize the marketing of similar products. For this purpose and prior to the registration of medicines or pharmaceutical products similar to those already authorized in Argentina or in any of the countries listed in Addendum I, the local Public Health Authority will request only the information listed below.

Once the information requested in this article is put forth, there will be a period of 120 calendar days for the Health and Welfare Department to issue a decision, counted as from the date when the application for registering the medicine or pharmaceutical product is filed.



Argentina
Not specified

Bolivia



Bolivia
Not specified



Andean Community Decision 486 (2000), Article 266

Decision 486, Article 266

Member Countries, when requiring, as a condition for approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against any unfair commercial use. In addition, member countries shall protect such data against disclosure, except “where necessary to protect the public, or unless steps are taken to ensure that the data is protected against unfair commercial use.

Member countries may take steps to guarantee the protection provided for under this article.

Andean Community Decision 632 (2006)

Decision 632, Article 1 – Any Member Country wishing to do so may include, among the measures referred to in the second paragraph of Article 266 of Decision 486, the establishment of time periods during which it shall not authorize a third party, without the consent of the person who originally submitted the test data, to market a product based on such information.

Brazil

Law 9.279 on Industrial Property; Title V, Crimes Against Industrial Property; Chapter VI, Protection Against Unfair Competition

Article 195

A crime of unfair competition is committed by he who:

XIV – divulges, exploits or uses, without authorization, the results of tests or other undisclosed data the elaboration of which involved considerable effort and which has been presented to government entities as a condition for approving the commercialization of products.



Brazil
Not specified



Canada
8 years



Food and Drug Regulations, Section C.08.004.1 (as amended)

- (3) If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug,
 - (a) the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and
 - (b) the Minister shall not approve that submission or supplement and shall not issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.
- (4) The period specified in paragraph (3)(b) is lengthened to eight years and six months if
 - (a) the innovator provides the Minister with the description and results of clinical trials relating to the use of the innovative drug in relevant pediatric populations in its first new drug submission for the innovative drug or in any supplement to that submission that is filed within five years after the issuance of the first notice of compliance for that innovative drug; and
 - (b) before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug, the Minister determines that the clinical trials were designed and conducted for the purpose of increasing knowledge of the use of the innovative drug in those pediatric populations and this knowledge would thereby provide a health benefit to members of those populations.
- (5) Subsection (3) does not apply if the innovative drug is not being marketed in Canada.
- (6) Paragraph (3)(a) does not apply to a subsequent manufacturer if the innovator consents to the filing of a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission by the subsequent manufacturer before the end of the period of six years specified in that paragraph.
- (7) Paragraph (3)(a) does not apply to a subsequent manufacturer if the manufacturer files an application for authorization to sell its new drug under section C.07.003.
- (8) Paragraph (3)(b) does not apply to a subsequent manufacturer if the innovator consents to the issuance of a notice of compliance to the subsequent manufacturer before the end of the period of eight years specified in that paragraph or of eight years and six months specified in subsection (4).
- (9) The Minister shall maintain a register of innovative drugs that includes information relating to the matters specified in subsections (3) and (4).



1000

1000 ml



Chile
5 years



Law 19,039 on Industrial Property (as amended by Law 19,996), Articles 89 through 91 (implemented in part by Decree No. 153 by the Ministry of Health (2005) that is not reproduced)

Article 89 – When the Institute of Public Health or the Agricultural and Livestock Service require the presentation of undisclosed test data or other information regarding the safety and efficacy of a pharmaceutical or chemical-agricultural product which utilizes a new chemical entity which has not been previously approved by the competent authority, said data will have the character of reserved, according to the current legislation.

The undisclosed nature is understood to be fulfilled if the data has been subjected to reasonable measures to keep it in that condition and the same is neither generally known nor easily accessible for individuals who belong to the circles where this information is normally used.

The competent authority will not be able to disclose or utilize said data to grant a sanitary registration or sanitary authorization to whoever does not hold the permission of the owner of the data for a time period of 5 years, for pharmaceutical products, and 10 years, for chemical-agricultural products, counted as from the first sanitary registration or sanitary authorization granted by the Institute of Public Health or by the Agricultural and Livestock Service, according to which it corresponds.

To enjoy the protection of this article, the undisclosed character of the referred test data shall be indicated expressly in the application for the sanitary registration or authorization.

Article 90 – New chemical entity is understood as that active principle which has not been previously included in sanitary registrations or authorizations granted by the Institute of Public Health or by the Agricultural and Livestock Service, according to which it corresponds, and which has not been commercialized in the national territory before the application for registration or sanitary authorization.

To the effects of this Paragraph, active principle is understood as that substance endowed with one or more pharmacological effects or with chemical-agricultural uses, whichever may be its form, expression, or disposition, including its salts and complexes. In no case will it be considered as a new chemical entity:

Those uses and therapeutic indications distinct from those authorized in other previous sanitary registrations or authorizations of the same chemical entity.

The changes in the way of administration or forms of dosage from those authorized in other previous sanitary registrations or authorizations of the same chemical entity.

The changes in the pharmaceutical forms, formulations or combinations of chemical entities already authorized or registered.

The salts, complexes, crystallized forms or those chemical structures which are based on a chemical entity with previous sanitary registration or authorization.

Chile

Article 91 – The protection of this Paragraph will not proceed, when:

The owner of the test data referred to in article 89 has incurred in conducts or practices declared contrary to free competition in direct relation to the utilization or exploitation of this information, according to a final decision of the Court of Defense of Free Competition.

For reasons of public health, national security, non-commercial public use, national emergency or other circumstances of extreme urgency declared by the competent authority, it is justified to put an end to the protection referred to in article 89.

The pharmaceutical or chemical-agricultural product is subjected to a compulsory license, in conformity with that established in this law.

The pharmaceutical or chemical-agricultural product has not been commercialized in the national territory after 12 months, counted as from the registration or sanitary permit obtained in Chile.

The pharmaceutical or chemical-agricultural product holds a registration or sanitary permit in a foreign country with more than 12 months of validity.

Colombia



Colombia
5 years



Data Protection Decree No. 2085 – September 19, 2002

By which are regulated aspects related to the information provided to obtain sanitary registration with respect to new chemical entities in the area of medicine:

Article 1 – For effects of the present decree, it is understood that a new chemical entity is an active principle that has not been included in Pharmacological Norms in Colombia.

Paragraph: New or second uses are not considered new chemical entities, not novelties or changes regarding the following aspects:

Pharmaceutical forms, indications or second indications, new combinations of known chemical entities, formulations, dosage forms, means of administration, modifications that imply pharmacokinetic changes, conditions of commercialization and packaging and in general those that imply new presentations.

Article 2 – Where the commercialization of a new chemical entity is approved, the related undisclosed information may not be used directly or indirectly as supporting information for the approval of another application relating to the same new chemical entity.

Paragraph: Generating the undisclosed information the use of which is protected hereby must have required considerable effort on the part of the person submitting same to the competent sanitary authority.

Article 3 – The protection of the undisclosed information covered by this decree shall be in the following form:

Three (3) years counted from the marketing approval in Colombia for those applications presented during the first year that this decree is in force.

Four (4) years counted from the marketing approval in Colombia for those applications presented during the second year that this decree is in force.

Five (5) years counted from the marketing approval in Colombia for those applications presented during the third year that this decree is in force.

Subject to this disposition, nothing will prevent carrying out summary approval procedures based on bioequivalence and bioavailability studies.

Article 4 – The protection referred to in this decree does not apply in the following cases:

When the holder of the sanitary registration of a new chemical entity has authorized the use of non-disclosed information as support for another subsequent application.

When the new chemical entity whose sanitary registration is applied for is similar to another that has been approved and commercialized in Colombia and the term of protection in Article 3 has expired.

When it is necessary to protect the public, as qualified by the Ministry of Health.

When the new chemical entity that is the object of the sanitary registration has not been commercialized in the country one year after the issuance of said commercialization authorization.

Colombia

Article 5 – The present decree takes forces from the date of its publication in the Official Daily and it will apply to applications for sanitary registrations presented from that date forward.

Treaty of Group of Three (Colombia, Mexico and Venezuela)

Article 18-22 Data Protection of Chemicals used for Pharmaceutical Purposes (Farmaquímicos) or Agroquímicos

If as a condition to approve the commercialization of Farmaquímicos or agroquímicos which use new chemical components, one Party demands the filing of data of experiments or any other data not published and necessary to determine its safety and efficiency, such Party will protect such data, provided its creation implies significant effort, except when the publication of such data is necessary to protect the public or when measures are taken to protect such data from an illegal use.

Each Party will provide, with respect to the data mentioned in 1 above, filed after the entry into effect of this Treaty, that no person, different from such one that filed the data, shall be able, without the authorization of the person that filed the data, to obtain such information to be used together with an approval request, during a reasonable period of time after the filing. For this purpose, it will be understood as a reasonable period of time, no less than a five-year term, starting from the date of the good's commercialization approval, taking into consideration the efforts and expenses incurred by the person who filed the data. Subject to this provision, nothing will impede one of the Parties from executing expedite approval procedures for such goods based on bioequivalence or biodisponibility studies.

Andean Community Decision 486 (2000), Article 266

Decision 486, Article 266 – Member Countries, when requiring, as a condition for approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against any unfair commercial use. In addition, member countries shall protect such data against disclosure, except “where necessary to protect the public, or unless steps are taken to ensure that the data is protected against unfair commercial use.

Member countries may take steps to guarantee the protection provided for under this article.

Andean Community Decision 632 (2006)

Decision 632, Article 1 – Any Member Country wishing to do so may include, among the measures referred to in the second paragraph of Article 266 of Decision 486, the establishment of time periods during which it shall not authorize a third party, without the consent of the person who originally submitted the test data, to market a product based on such information.

Costa Rica



Costa Rica
5 years



Regulations for the Undisclosed Information Law

Article 9. Abbreviated Documentation for the Authorization of a Pharmaceutical Preparation⁴

1. There shall be no authorization of pharmaceutical preparations with respect to which the applicant does not submit data regarding the pharmacological, toxicological, and clinical tests necessary to document the efficacy, quality, and safety of the medication, without prejudice to the instances contemplated by the following subsection.
2. The applicant in a process for the authorization of a pharmaceutical preparation who does not provide all toxicological, pharmacological, and clinical tests to determine that the medication meets efficacy, quality, and safety requirements must meet at least one of the following two conditions:
 1. Submission of a declaration of consent by the owner of the reference pharmaceutical preparation authorized on the basis of a complete documentation process. Said declaration of consent issued by the owner of the original or reference pharmaceutical preparation shall authorize health authorities to utilize the pharmacological, toxicological, and clinical documentation in the complete reference documentation for the purpose of evaluating the application for the pharmaceutical preparation in question.
 2. Documentation that the pharmaceutical preparation that is the subject of the application is essentially similar to the reference pharmaceutical preparation, which must be authorized and marketed in a Central American State for a minimum period of five years.

In the event that the pharmaceutical preparation is designated for a different therapeutic use or is to be administered by different means or in different dosages in comparison with the reference pharmaceutical preparation, the results of the appropriate pharmacological, toxicological, and clinical tests must be provided.

Article 10. Mandatory Licenses after the Expiration of the Period

1. A health authority may provide for the granting of non-exclusive mandatory licenses that make it possible to obtain authorizations for the sale of pharmaceutical preparations without the need to comply with the five year data protection period. A mandatory licensee shall be exempt from compliance with the five year period provided by the foregoing Article, but it shall not be authorized to access the sale authorization documentation for the reference pharmaceutical preparation.
2. Said mandatory licenses may be granted for serious public health protection reasons, as a treatment for epidemics or similar phenomena; the insufficiency of the commercial utilization of the medication in the country, and when the Competition Promotion Board has ruled that the owner of the reference pharmaceutical preparation has engaged in practices to restrain competition in relation to the medication in question.
3. Mandatory licenses shall be subject to compensation. The royalty fee that must be paid by the mandatory licensee to the holder of sale authorization shall be appropriate to the circumstances of the case and shall be determined by the cognizant agency, without prejudice to the opportunity for review by the courts. When the mandatory license is based on a violation of competition protection provisions, the Competition Promotion Board shall determine the terms and conditions of same.

⁴ These implementing regulations have not yet passed.

Costa Rica

Article 11. Definition of an Essentially Similar Medication

1. The pharmaceutical preparation evaluated shall be deemed essentially similar to another prior or reference pharmaceutical preparation when it meets the criteria of identity of quantitative and qualitative composition with respect to principal active ingredients or medicinal substances, identity of pharmaceutical form, and therapeutic equivalence.
2. The various oral pharmaceutical forms for immediate release may be deemed to be the same pharmaceutical form, provided that their bioequivalence has been demonstrated.
3. Therapeutic equivalence to the reference pharmaceutical preparation shall be documented by the pertinent bioequivalence studies or, if applicable, bioavailability studies.

Article 12. Documentation of Data Exclusivity Compliance

1. Documentation files that do not contain all of the pharmacological, toxicological, and clinical tests necessary to obtain authorization for sale and which are not based on consent by the holder of the registration of the reference pharmaceutical preparation may only be authorized when the specific data exclusivity period has been respected.
2. The cognizant governmental authority shall conduct an official examination to determine that applications submitted on the basis of Subsection 3 of Article 2 have complied with the data protection period. If the application is submitted prior to the expiration of the data exclusivity period, the application shall be rejected outright. In such instances, it shall not be lawful or appropriate to return the application processing fee.
3. For the purposes and effects provided by this Article, the necessary coordination with other Central American health authorities shall be achieved, and there shall be published a list of principal active ingredients authorized on the basis of a complete documentation file and with respect to which a period of five years following the initial authorization for sale has elapsed.

Dominican Republic



Dominican
Republic
5 years



Law 20-00 on Industrial Property

Article 181. Information and data protection for marketing approval

1. When the national competent authority requires or permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy of said product, the National Competent Authority shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Dominican Republic.
2. When the national competent authority permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, said National Competent Authority shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) the evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date the approval was granted in the Dominican Republic to the person who received approval in the other territory. In order to receive protection under this paragraph 2, it shall be required that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory.
3. The national competent authority shall protect the undisclosed information against disclosure except where necessary to protect the public, and it may not consider the information accessible within the public domain as undisclosed data. Notwithstanding the foregoing, if any undisclosed information concerning safety and efficacy submitted to the national competent authority, or an entity acting on behalf of the national competent authority, for purposes of obtaining marketing approval is disclosed by such entity, the national competent authority shall protect such information from unfair commercial use in the manner set forth in this Article.
4. For purposes of this Article, a new product is one that does not contain a chemical entity that has been previously approved in the Dominican Republic. A chemical entity does not mean an inactive ingredient that is contained in a new pharmaceutical product.

DR-CAFTA – Art. 15.10(1)(b):

If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date approval was granted in the Party's territory to the person who received approval in the other territory. In order to receive protection under this subparagraph, a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory.

Ecuador

Law No. 2006-13 on Industrial Property and Rights of the Author, Article 286

Article 286 – It is also considered unfair competition act, regardless of appropriate action for violation of undisclosed information, any act or practice that takes place in the execution of economic activities which consists of or has as result:

- a) The unfair commercial use of undisclosed data proof or other secret data which production involves a considerable effort and which have been submitted to the competent authority for the purpose of obtaining marketing approval of pharmaceutical products or chemical, agricultural or industrial products;
- b) The disclosure of such data, except when necessary for protecting the public and the due measures are taken to ensure the protection of data against all unfair commercial use, and
- c) The unauthorized removal of data which production involves a considerable effort for its commercial use in an unfair manner.

Andean Community Decision 486 (2000), Article 266

Decision 486, Article 266 – Member Countries, when requiring, as a condition for approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against any unfair commercial use. In addition, member countries shall protect such data against disclosure, except “where necessary to protect the public, or unless steps are taken to ensure that the data is protected against unfair commercial use.

Member countries may take steps to guarantee the protection provided for under this article.

Andean Community Decision 632 (2006)

Decision 632, Article 1 – Any Member Country wishing to do so may include, among the measures referred to in the second paragraph of Article 266 of Decision 486, the establishment of time periods during which it shall not authorize a third party, without the consent of the person who originally submitted the test data, to market a product based on such information.



Ecuador
Not specified

El Salvador



El Salvador
5 years



Law on the Promotion and Protection of Intellectual Property, Decree No. 604 (1993) as amended by Article 103 of Legislative Decree No. 912 (2005), Articles 181-A through 181 – E

Art. 181-A – As a condition for approving the marketing of new pharmaceutical or agricultural chemical products that use new chemical entities, it shall be necessary to file or other undisclosed data about the safety and efficacy of the products, the preparation of which supposes a considerable effort, the aforementioned data shall be protected from any unfair commercial use for a period of five years for pharmaceutical products and ten years for agricultural chemical products, from the date of approval for marketing in El Salvador.

Any authorities with whom test or other undisclosed data is filed shall not authorize third parties to market products based on the information or the approval granted to the person who initially filed said information, if they do not have the consent of the person who provided the information.

Any authorities with whom test or other undisclosed data is filed shall not authorize third parties to market products based on the information or the approval granted to the person who filed said information, if they do not have the consent of the person who initially filed the information or obtained the approval for marketing.

Whoever requests approval for marketing a pharmaceutical product must provide the authorities with a list of all the patents covering the product or its approved use.

Art. 181-B – If, as a condition for approval of the marketing of new pharmaceutical or agricultural chemical products, third parties are permitted to provide evidence of the safety and efficacy of a product previously approved in El Salvador or another country, such as evidence of prior marketing approval; the authorities with whom the evidence is filed shall not permit third parties who do not have the consent of the person who obtained approval in El Salvador or the other country previously, to obtain authorization or to market a product on the basis of: 1) evidence of prior marketing approval in another country; or 2) information relating to the safety and efficacy delivered previously to obtain approval for marketing in El Salvador or another country; for a period of five years for pharmaceutical products and ten years for agricultural chemical products, from the date on which the approval was granted in El Salvador to the person who received approval in that other country.

In order to be able to receive protection under this article, the person who provides the information in the other country shall be required to request approval in El Salvador within five years following the date of approval for marketing in that other country.

Art. 181-C – For the purposes of the application of articles 181-A and 181-B, a new product shall be understood to be a product that does not contain a chemical entity that has been tested previously for marketing in the country.

El Salvador

Art. 181-D – The undisclosed information referred to in articles 181-A and 181-B shall be protected from any disclosure, except when necessary to protect the public and measures have been adopted to guarantee the protection of the data against any unfair commercial use.

Notwithstanding the provisions of the preceding paragraph, if any undisclosed information about the safety and efficacy filed with any authorities in order to obtain approval for marketing is disclosed by said authorities, said information will continue to be protected from all unfair commercial use, as is established in articles 181-A and 181-B.

Art. 181-E – As a condition for approving the marketing of a pharmaceutical product El Salvador, other persons who are not the person who originally filed the information on safety and efficacy shall be permitted to rely on evidence or information relating to the safety and efficacy of a product that was previously approved, such as evidence of prior approval of marketing in El Salvador or another country; the authorities shall not approve marketing of the product unless one of the following requirements is filed along with the application:

- a. Notarized affidavit which proves that there is no patent in force in El Salvador covering the product previously approved for marketing in the country or its approved use;
- b. Written authorization from the owner of the patent, in the event that there is a valid patent in El Salvador; or
- c. Notarized affidavit that there is a patent, the date on which it expires and indication that the applicant will not enter the market prior to the date of expiration of same; under said circumstances the authorities may approve marketing at the time of expiration of the patent.

Guatemala



Guatemala
5 years



Decree 57-2000, Law on Industrial Property, Articles 177 through 177(fifth), as amended.

Article 177 – (Amended by Article 1, Decree No. 30-2005; part “c” subsequently amended by Article 67, Decree No. 11-2006; all of the Congress of the Republic of Guatemala.)

Protection of test data. In order for an individual or legal entity to obtain approval to market a new pharmaceutical or agricultural chemical product, it must:

- a) Submit, if the authorities so require, test data or undisclosed information on safety and efficacy. The authorities will not approve marketing to third parties absent the consent of the owner or holder of the test data, for five years for pharmaceutical products and ten years for agricultural chemical products, as of the date of approval in this country; or,
- b) Submit, if the authorities so require, information relative to the safety and efficacy of a product previously approved in another country, such as that country’s prior marketing approval. The authorities will not approve marketing to third parties absent the consent of the holder of the test data or the marketing approval of another country, for five years for pharmaceutical products and ten years for agricultural chemical products, as of the date of approval in Guatemala.
- c) In order to grant the protection stipulated in part b) above, the administrative authorities will demand that the holder of the test data or marketing approval from another country request approval within five (5) years subsequent to having obtained such marketing approval in the other country.

Article 177 Second – (Supplemented by Article 2, Decree No. 09-2003, amended by Article 3, Decree No. 34-2004 and subsequently by Article 4, Decree 30-2005, all of the Congress of the Republic of Guatemala.)

Exception to the obligation to not disclose test data. The following are excepted from the obligation to not disclose test data or other undisclosed data:

- a) For pharmaceutical products, when it is necessary to protect user safety, life, or health in cases of a declared national emergency.
- b) For agricultural chemical products, in cases of declared national emergency or to protect user safety, the health or life of humans, animals, plants, or the environment.
- c) When the holder of the non-disclosed information or test data or of the health or phytosanitary record who might benefit from the protection has given written, notarized consent.

Article 177 Third – (Originally supplemented by Article 3, Decree No. 30-2005 of the Congress of the Republic of Guatemala. Subsequently amended by Article 68, Decree No. 11-2006 of the Congress of the Republic of Guatemala.)

As an exception to the protection of non-disclosed information or non-disclosed test data, the corresponding competent authority may not protect non-disclosed information or non-disclosed test data in the case of pharmaceutical or agricultural chemical products when they correspond to new or secondary uses, or to indications of a chemical product or entity or new combinations of approved chemical entities.

Guatemala

Article 177 Fourth – (Supplemented by Article 4, Decree No. 30-2005 of the Congress of the Republic of Guatemala.)

For purposes of the above articles, the following definitions will hold:

- a) Undisclosed information or test data: Information or data that may or may not be, in whole or in part, business secrets in the sense of Decree Number 57-2000 of the Congress of the Republic and which is used to demonstrate the safety and efficacy of a pharmaceutical or agricultural chemical product.
- b) New product: One containing a chemical entity not previously approved in this country.

Article 177 Fifth – (Amended by Article 69, Decree No. 11-2006 of the Congress of the Republic of Guatemala.)

When the applicable regulation permits parties other than the party that originally submitted the safety and efficacy information to rely on evidence or information relating to the safety and efficacy of a previously approved product, such as evidence of prior commercial approval in Guatemala or in another country, as a condition for approving the marketing of a pharmaceutical product, the corresponding administrative authority:

- a) Will apply, in its approval process, measures aimed at preventing the marketing by such other parties of a product protected by a patent covering the previously approved product or its approved use during the period of such patent, unless the patent holder provides consent or approval; and
- b) Will provide that the patent holder be informed of the request and identity of any other party requesting approval to enter the market during the period of a patent that, according to the information the holder has provided, has been identified as covering the approved product or its approved use.

Honduras



Honduras
5 years



Decree No. 16-2006, Law on the Application of the Free Trade Treaty between the Dominican Republic, Central America and the United States

Title IV: Measures Related to Certain Regulated Products Sole Chapter: Protection of Undisclosed Data or Information

Article 19 – If a cognizant national authority approves the marketing of a new pharmaceutical product or agricultural chemical product on the basis of undisclosed information submitted directly to said authority (and it is not based on data regarding the safety and effectiveness of a product previously approved in another country), related to the safety and effectiveness of said product, said national authority shall not permit third parties that do not have the consent of the person that provided the information, to sell a product on the basis of (1) the information or (2) the approval granted to the person that submitted the information, for a period of five (5) years for pharmaceutical products, and ten (10) years for agricultural chemical products, following the date of approval in Honduras.

Article 20 – If the cognizant national authority approves the marketing of new pharmaceutical products or agricultural chemical products on the basis of evidence of the safety and effectiveness of a product previously approved in another country, such as evidence of prior marketing approval in said other country, said national authority shall not permit third parties that do not have the consent of the person that previously obtained said approval in the other country, to obtain approval or to market a product on the basis of (1) evidence of the prior marketing approval in the other territory; or (2) information regarding safety or effectiveness submitted previously for the purpose of obtaining marketing approval in the other country, for a period of five (5) years in the instance of pharmaceutical products, and ten (10) years in the instance of agricultural chemical products, following the date on which the cognizant national authority authorized or approved marketing in Honduras by the person that received the approval in the other country.

In order to be able to receive protection under this Article, it shall be required that the person that provided the information in the other country apply for approval in Honduras within five (5) years following the date of the marketing approval in the other country.

Article 21 – For the purposes and effects of implementation of Articles 19 and 20 of this Law, a new product shall be understood to be a product that does not contain a chemical component which has been previously approved for marketing in Honduras.

Article 22 – A person that applies for marketing approval for a new pharmaceutical product must provide to the cognizant national authority a list of all the patents covering said product or the approved use of same.

Article 23 – The cognizant national authority shall protect undisclosed information or evidentiary data against disclosure, except when it is necessary in order to protect the public. In such a situation, it shall protect said undisclosed information or evidentiary data against improper commercial use by third parties, in compliance with Articles 19 and 20 of this Law. Information available in the public domain cannot be considered to be undisclosed data.

Honduras

Article 24 – If, in compliance with Articles 19 and 20 of this Law, the cognizant national authority, for the purpose of approving marketing of a pharmaceutical product, permits persons other than the person that originally submitted the information regarding safety or effectiveness, to base its application on evidence or information regarding the safety and effectiveness of a product that was previously approved (such as evidence of prior marketing approval in Honduras or in another country), said cognizant national authority must require that the following be submitted:

- a) A statement sworn before a notary which states for the record that there is no patent in effect in Honduras that covers the product approved for marketing in the county or its approved use.
- b) If there is such a patent in effect in Honduras, written authorization of the holder of said patent, which authorizes marketing of the pharmaceutical product.
- c) A statement sworn before a notary that there is such a patent, the date on which the latter expires, and an indication that the applicant shall not enter the market prior to the expiration date of same; under said circumstances the cognizant national authority may grant marketing approval effective on the day following the expiration date of the patent.

The cognizant national authority shall require that the aforementioned sworn statements and authorizations be made with reference to the patents, if any, identified for said authority, in compliance with Article 22 of this Law, by the person that originally submitted the information on safety and effectiveness. For such purposes and effects, the national authority shall make available the list of patents described in Article 22.

If the application is submitted with a sworn statement in compliance with Subsection a) or written authorization in compliance with Subsection b), procedures for marketing approval or authorization shall proceed.

If the application is submitted accompanied by the sworn statement contemplated by Subsection c), the cognizant national authority may examine the application, but shall not grant marketing approval until expiration of the patent's period of protection.



Mexico
5 years



Industrial Property Law (as amended) Article 86bis

The information required by the special laws that determine the safety and efficacy of pharmaceutical and agrochemical products that utilize new chemical components shall be protected under the terms of international treaties to which Mexico is a party.

Article 1711. Trade Secrets. NAFTA

If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

Treaty of Group of Three (Colombia, Mexico and Venezuela)

Article 18-22 Data Protection of Chemicals used for Pharmaceutical Purposes (Farmaquímicos) or Agrochemicals

1. If as a condition to approve the commercialization of Farmaquímicos or agrochemicals which use new chemical components, one Party demands the filing of data of experiments or any other data not published and necessary to determine its safety and efficiency, such Party will protect such data, provided its creation implies significant effort, except when the publication of such data is necessary to protect the public or when measures are taken to protect such data from an illegal use.
2. Each Party will provide, with respect to the data mentioned in 1 above, filed after the entry into effect of this Treaty, that no person, different from such one that filed the data, shall be able, without the authorization of the person that filed the data, to obtain such information to be used together with an approval request, during a reasonable period of time after the filing. For this purpose, it will be understood as a reasonable period of time, no less than a five-year term, starting from the date of the good's commercialization approval, taking into consideration the efforts and expenses incurred by the person who filed the data. Subject to this provision, nothing will impede one of the Parties from executing expedite approval procedures for such goods based on bioequivalence or biodisponibility studies.

Nicaragua

Health Ministry Resolution No. 115-2006

If, as a condition for the approval of a new pharmaceutical product, the presentation of non-disclosed data or information on safety and efficacy is demanded, the entities indicated above, or their successors, will not allow third parties who lack the consent of the party providing the information to sell the product based on the information or approval granted to the party that presented the information, for a period of five years for a new pharmaceutical product, with such period to begin counting as of the date of approval for sale in Nicaragua.

A party requesting approval for sale of a pharmaceutical product must provide the health authorities with a list of patents protecting such product or its approved use, with such list to be sent for verification to the Intellectual Property Registry.

If, as a condition for approving the sale of a new pharmaceutical product, any of the aforementioned entities allows third parties to give evidence as to the safety or efficacy of a product previously approved in another country, such as evidence of prior approval for sale, the entity will not allow third parties that lack the consent of the party that obtained such prior approval in the other country to obtain authorization or sell a product based on (1) evidence of prior approval for sale in the other country, or (2) information on safety or efficacy submitted previously to obtain approval for sale in the other country, for a period of at least five years for a new pharmaceutical product after the date the approval was granted in Nicaragua to the party that received the approval in the other country. In order to be entitled to the protection of this paragraph, the authorities may require that the party that provides the information in the other country request approval in Nicaragua, within five years after the approval date in the other country.

If any non-disclosed information or test data on safety and efficacy presented to the aforementioned entities, for purposes of obtaining approval for sale, is disclosed by such institutions, such information must always be protected against any unfair commercial use in accordance with the above provisions.

If, as a condition for approving the sale of a pharmaceutical product in Nicaragua, before expiration of the five-year protection period, parties other than the party that originally presented the information on safety or efficacy are permitted to use evidence or information on the safety and efficacy of a product that was previously approved, such as evidence of prior approval for sale in Nicaragua or in another country, the authority may approve sale of the product, provided that the following documents are submitted with the request for approval:

- a) A sworn statement that no valid patent exists in Nicaragua protecting the product previously approved for sale in Nicaragua or its protected use.
- b) If there is a valid patent registered in Nicaragua, written authorization from the patent holder, and
- c) A sworn statement attesting to the existence of the patent, its expiration date, and a statement that the applicant will not sell the product prior to the patent expiration date; under these circumstances, the authority may grant approval for sale at the time the patent expires.



Nicaragua
5 years

Panama



Panama
5 years



Legislative Assembly Law No. 23, 2009

Section 7: Protection of Undisclosed Information Article 39

1. In guaranteeing effective protection against unfair competition, in conformity with the provisions of Article 10bis of the Paris Agreement of 1967, the Members shall protect undisclosed information, in conformity with paragraph 2 and data submitted to government or official agencies, in conformity with paragraph 3.
2. Individuals and legal entities shall have the possibility of preventing information legitimately under their control from being divulged to third parties or being acquired or used by third parties without their consent in a manner contrary to honest trade practice, insofar as said information:
 - a) is secret, in the sense of not being generally known, as a whole or in the exact configuration and combination of its components, or easily accessible by persons in circles in which the type of information in question is normally used; and
 - b) has a commercial value because it is secret; and
 - c) has been the subject of measures reasonable under the circumstances, and taken by the person who lawfully controls it, to keep it secret.
3. When the Members require, as a condition for approval of the sale of pharmaceutical products or chemical agricultural products that use new chemical entities, the filing of undisclosed test and other data the assembling of which requires a considerable effort, they shall protect these data from any unfair trade use. In addition, the Members shall protect these data from any disclosure except as may be necessary to protect the public, unless measures are adopted to ensure protection of the data from any unfair trade use.





Peru
5 years



Legislative Decree 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.

Peru

Andean Community Decision 486 (2000), Article 266

Decision 486, Article 266 – Member Countries, when requiring, as a condition for approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against any unfair commercial use. In addition, member countries shall protect such data against disclosure, except “where necessary to protect the public, or unless steps are taken to ensure that the data is protected against unfair commercial use.

Member countries may take steps to guarantee the protection provided for under this article.

Andean Community Decision 632 (2006)

Decision 632, Article 1 – Any Member Country wishing to do so may include, among the measures referred to in the second paragraph of Article 266 of Decision 486, the establishment of time periods during which it shall not authorize a third party, without the consent of the person who originally submitted the test data, to market a product based on such information.

Trinidad and Tobago



Protection Against Unfair Competition Act 27/1996

- (4) Any act or practice, in the course of industrial or commercial activities, shall be considered an act of unfair competition if it consists or results in:
- (a) an unfair commercial use of secret test or other data, the origination of which involves considerable effort and which have been submitted to a competent authority for the purposes of obtaining approval of the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities; or
 - (b) the disclosure of such data, except
 - i. where necessary to protect the public; and
 - ii. where steps are taken to ensure that the data are protected against unfair commercial use.

Trinidad and
Tobago
Not specified



United States

Federal Food, Drug, and Cosmetic Act, Section 505 [21 U.S.C. 355] (c) (3)(F)

- (ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.
- (iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.
- (iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

Public Health Service Act, Section 351 (42 U.S.C. 262)

- (k)(7) Exclusivity for reference product.
 - (A) Effective date of biosimilar application approval. – Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).
 - (B) Filing period. – An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).
 - (C) First licensure. – Subparagraphs (A) and (B) shall not apply to a license for or approval of
 - (i) a supplement for the biological product that is the reference product; or
 - (ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for
 - (I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or
 - (II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.



United States
5 or 12 years

Venezuela



Venezuela
5 years



Treaty of Group of Three (Colombia, Mexico and Venezuela)⁵

Article 18-22 Data Protection of Chemicals used for Pharmaceutical Purposes (Farmoquímicos) or Agroquímicos

1. If as a condition to approve the commercialization of Farmquímicos or agrochemicals which use new chemical components, one Party demands the filing of data of experiments or any other data not published and necessary to determine its safety and efficiency, such Party will protect such data, provided its creation implies significant effort, except when the publication of such data is necessary to protect the public or when measures are taken to protect such data from an illegal use.
2. Each Party will provide, with respect to the data mentioned in 1 above, filed after the entry into effect of this Treaty, that no person, different from such one that filed the data, shall be able, without the authorization of the person that filed the data, to obtain such information to be used together with an approval request, during a reasonable period of time after the filing. For this purpose, it will be understood as a reasonable period of time, no less than a five-year term, starting from the date of the good's commercialization approval, taking into consideration the efforts and expenses incurred by the person who filed the data. Subject to this provision, nothing will impede one of the Parties from executing expedite approval procedures for such goods based on bioequivalence or biodisponibility studies.

⁵ The legal status of the Treaty of the Group of Three is unclear in Venezuela.



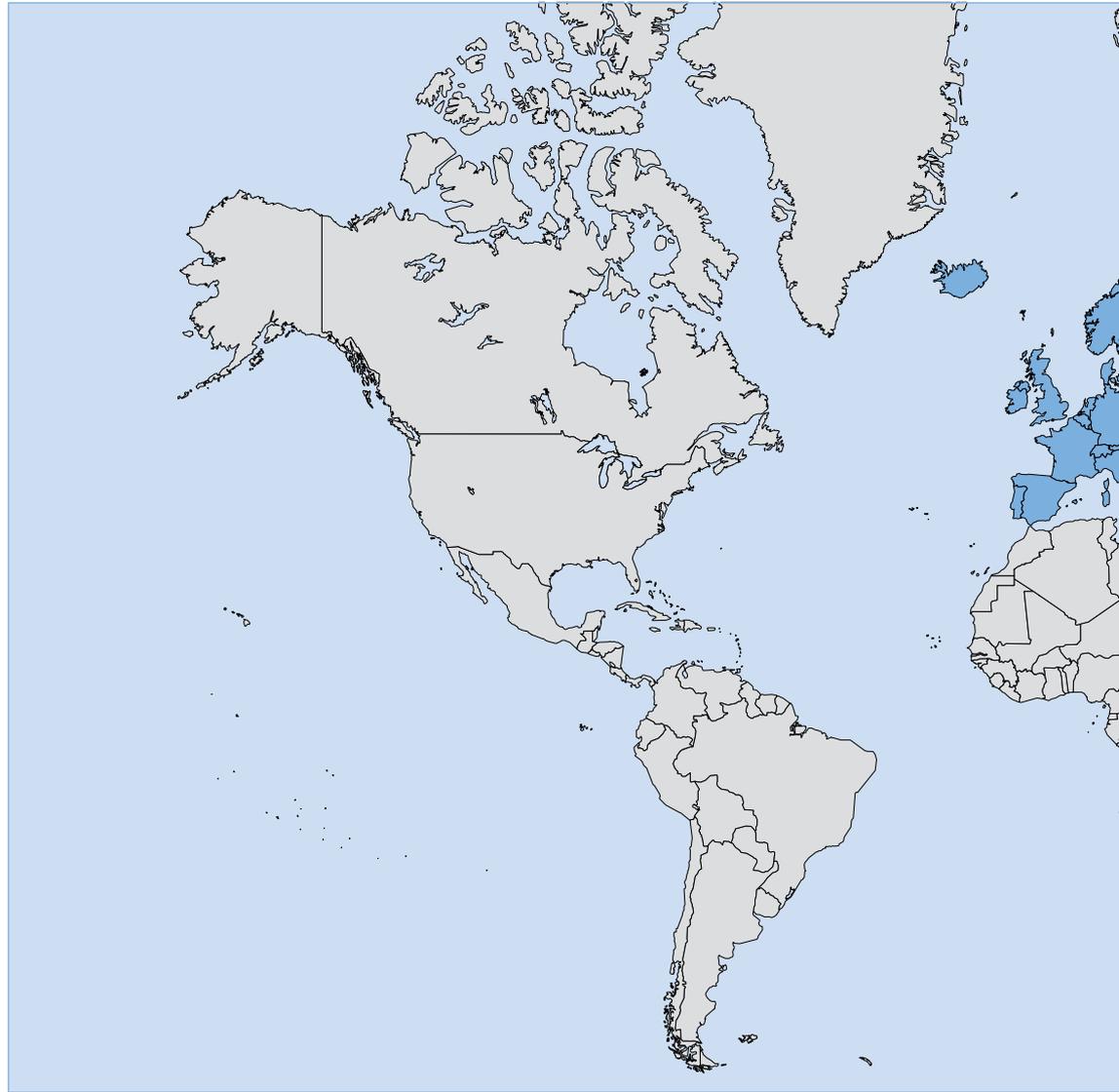
Croatia



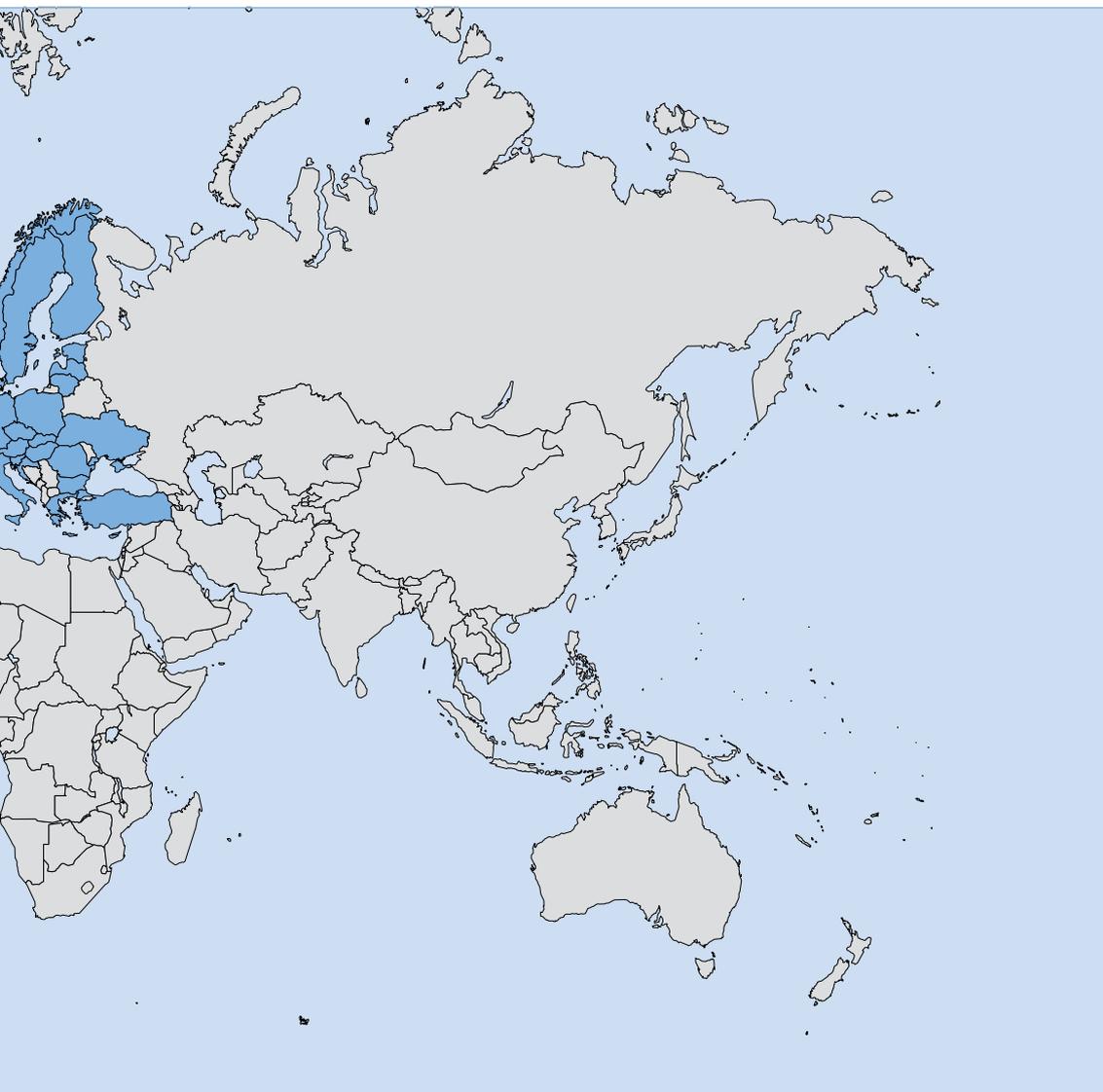
European Union
and European
Economic Area



Switzerland



Europe



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Law on Medicines and Medical Products, Article 15

The applicant requesting a marketing authorisation to place a medicine from Article 14 of this Act on the market, shall not be required to provide the results of toxicological and pharmacological tests or results of clinical trials if he can demonstrate either

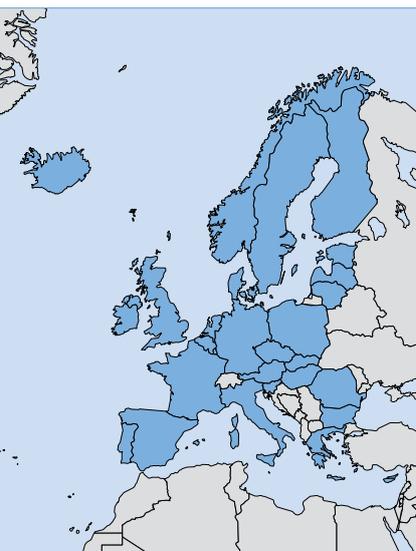
- a) that the finished medicine is equivalent to the finished medicine of the original manufacturer under the condition that the original manufacturer of the finished medicine was granted the marketing authorization in the Republic of Croatia or in any Member State of the European Union six or more years ago and that the finished medicine was marketed in the Republic of Croatia.

Croatia
6 years





European Union and European Economic Area



On March 31, 2004, the EU adopted new pharmaceutical legislation under Directive 2004/27/EC and introduced a new data exclusivity system for original medicines. The new system introduces a period of data exclusivity of 8 years (protecting against filing of a generic application), and then an additional 2 year exclusivity provision (protecting against marketing of the generic). This effective 10-year exclusivity period can be extended by an additional one year if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which are held to bring a significant clinical benefit in comparison with existing therapies. This is referred to as the 8+2+1 formula and is applicable in all EU and EEA Member States for innovative products for which the application for marketing authorization was submitted as from October 30 or November 20, 2005.

For the protection of innovative products for which the marketing authorization was submitted to national authorities before October 30, 2005, the Member States could choose between a period of data exclusivity (protecting against filing of a generic application) of ten years, six years, or six years but limited to the duration of the patent protecting the product⁶. Products approved by the EMA and European Commission under the centralized procedure on the basis of an application for marketing authorization submitted before November 20, 2005 benefit from ten years of data exclusivity (protecting against filing of a generic application). Ten years of data exclusivity provides protection against generic competition for a period equal to ten years plus the review time needed to approve the generic product.

APPLICABLE LEGISLATION FOR PRODUCTS SUBMITTED FOR APPROVAL BEFORE OCTOBER 30/ NOVEMBER 20, 2005:

Article 10(1)(a)(iii) of Directive 2001/83/EC prior to amendment by Directive 2004/27/EC (applies to products submitted for approval via Mutual Recognition and National procedures BEFORE October 30, 2005)

In derogation of Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property: (a) The applicant shall not be required to provide the results of toxicological and pharmacological tests or the results of clinical trials if he can demonstrate: (iii) that the medicinal product is essentially similar to a medicinal product which has been authorised within the community, in accordance with community provisions in force, for not less than six years and is marketed in the Member State for which the application is made. This period shall be extended to 10 years in the case of high technology medicinal products having been authorised according to the procedure laid down in Article 2(5) of Council Directive 87/22/EEC. Furthermore, a Member State may also extend this period to 10 years by a single Decision covering all medicinal products marketed on its territory where it considers this necessary in the interest of public health. Member States are at liberty not to apply the six-year period beyond the date of expiry of a patent protecting the original medicinal product.

Austria (EU)	
10 years	
Belgium (EU)	
10 years	
Bulgaria (EU)	
10 years	
Cyprus (EU)	
10 years	
Czech Rep. (EU)	
10 years	
Denmark (EU)	
10 years	
Estonia (EU)	
10 years	
Finland (EU)	
10 years	
France (EU)	
10 years	
Germany (EU)	
10 years	
Greece (EU)	
10 years	
Hungary (EU)	
10 years	

⁶ Belgium, France, Germany, Italy, Luxembourg, the Netherlands, Sweden and the UK chose for a general ten-year data exclusivity period. The other Member States chose for six years (sometimes limited to patent life). Despite the 6-year period adopted by Spain in its domestic law in 1993, it operates a special, separate administrative arrangement whereby a "generic pharmaceutical specialty" will not generally be granted authorization until 10 years have elapsed since authorization of the original, innovative product in Spain, or when the drug is authorized as a generic in an EU country where product patent protection for the active principle could have been obtained. This is reflected in Circular 3/1997 of February 1997 on the procedure for generic drug applications, from Directorate General of Pharmaceuticals and Health Products in Spain. The terms of the circular are, however, vague and its legal value has been contested.

European Union and European Economic Area

Article 13(4) of Regulation (EEC) No. 2309/93 (applies to products submitted for approval via the Centralized Authorization Procedure BEFORE November 20, 2005)

Medicinal products which may have been authorized by the Community in accordance with the provisions of this Regulation shall benefit from the ten-year period of protection referred to in point 8 of the second paragraph of Article 4 of Directive 65/65 (which has been superseded by Article 10.1(a)(i) of Directive 2001/83/EC).

APPLICABLE LEGISLATION FOR PRODUCTS SUBMITTED FOR APPROVAL AFTER OCTOBER 30/ NOVEMBER 20, 2005:

Article 14.11 of Regulation 726/2004 (applies to products submitted for approval via the Centralized Authorization Procedure from November 20, 2005)

Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorized in accordance with the provisions of the Regulation shall benefit from an eight-year period of data protection and a ten-year period of marketing protection, in which connection the latter period shall be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Article 10.1 & 10.5 of Directive 2001/83 (applies to products submitted for approval via the Mutual Recognition Procedure, National Approval Procedure or Decentralized Approval Procedure from October 30, 2005)

10.1 – By way of derogation from Article 8(3)(i) and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorized under Article 6 for not less than eight years in a Member State or in the Community.

A generic medicinal product authorized pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorization of the reference product. The first subparagraph shall also apply if the reference medicinal product was not authorized in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been authorized. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month, a confirmation that the reference medicinal product is or has been authorized together with the full composition of the reference product and if necessary other relevant documentation.

The ten year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which during the scientific evaluation prior to their authorization are held to bring significant clinical benefit in comparison with existing therapies.

10.5 – In addition to the provisions laid down in paragraph 1, where an application is made for a new indication for a well established substance, a non-cumulative period of one year of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indications.

	Iceland (EEA) 10 years
	Ireland (EU) 10 years
	Italy (EU) 10 years
	Latvia (EU) 10 years
	Liechtenstein (EEA) 10 years
	Lithuania (EU) 10 years
	Luxembourg (EU) 10 years
	Malta (EU) 10 years
	Norway (EEA) 10 years
	Netherlands (EU) 10 years
	Poland (EU) 10 years
	Portugal (EU) 10 years
	Romania (EU) 10 years
	Slovakia (EU) 10 years
	Slovenia (EU) 10 years
	Spain (EU) 10 years
	Sweden (EU) 10 years
	UK (EU) 10 years



Switzerland
10 years



Decree on Medications – Section 3, Article 17

In the case of an application for approval of a medication that is essentially the same as an already approved medication (original preparation) and is designed for the same use, the application can be based on the results of its pharmacological, toxicological, and clinical tests, if:

- a. The permit holder of the original preparation approves in writing; or
- b. Ten years have passed since the approval of the original preparation.

If a new indication, a new method of administration, a new method of dispensing, a new dosage, or application to a new target animal species has been approved, an application as described in paragraph 1 can be based on the pertinent test results if:

- a. The permit holder of the original preparation approves in writing; or
- b. Three years have passed since the approval of the original preparation.

Upon request the Institute shall extend the protective period under paragraph 2-b to five years if a significant therapeutic improvement is achieved thanks to the new method of administration, a new method of dispensing, new dosage, or application to a new target animal species.

The protective term is indicated with the permit.

Turkey

Regulations on Licensing the Human Medical Products

Article 9 – Abbreviated License

- 3) that the medical product is similar to a medical product licensed with expired data privilege period under the provisions of the legislation in force. “The data protection period as stipulated under this paragraph is valid for the products for which no generic license application was filed in Turkey until 1/1/05 among the original products authorized for the first time in any of the Territory of the Customs Union after 1/1/01 and the original products to be licensed for the first time in any of the countries of the Territory of the Customs after 1/1/05 and such period is 6 (six)years starting with the date of initial authorization in the Territory of the Custom Union, provided that it shall be limited to the patent period of the molecule in Turkey.



Turkey
6 years



Ukraine
5 years



The Law of Ukraine – On Amending Article 9 of the Law of Ukraine “On Medicines”

Verkhovna Rada of Ukraine has resolved:

I. To amend Article 9 of the Law of Ukraine “On Pharmaceuticals” (published in the Bulletin of Verkhovna Rada, Issue 22, 1996, Art 86) as follows:

Article 9 – State registration of medicines

Information contained in the application for the state registration of the medicine and its attachments (hereinafter the registration data) shall be protected by the state under the provisions of this law and other Ukrainian regulations from its disclosure and commercial use in bad faith. The Ministry of Health of Ukraine or bodies authorized by it shall protect such information from its disclosure and prevent its commercial use in bad faith.

If the medicine has been registered in Ukraine, it shall be prohibited to use its registration data for the filing of an application for the state registration of another medication within five years following such a registration (regardless of the duration of any patent related to such a medication), except for the cases where the right to refer to or to use such information has been acquired in accordance with the established procedure.

Disclosure and unauthorized use of the registration data involves disciplinary, administrative, civil and/or criminal liability under the provisions of the respective laws of Ukraine.

For the state registration of medications based on or related to an intellectual property object for which a patent was granted under Ukrainian laws, the applicant shall submit a copy of such Letters Patent or a copy of a license allowing them to produce and sell the registered medications. The Applicant shall provide a statement of non-infringement of third party's rights protected by patent due to such registration.

The applicant shall be given a Certificate for the registered medicine, specifying the period of validity within which the medicine shall be permitted for use in Ukraine.

The medicine may be used in Ukraine within the period of five years from the date of its state registration. At request of the person having submitted the application for state registration the term, within which it is permitted for use in Ukraine, may be reduced in accordance with the registration authority.

Should previously unknown dangerous properties of the medicine be detected, the Ministry of Health of Ukraine or the body authorized by the Ministry may take the decision to prohibit (totally or provisionally) the use of the medicine in Ukraine.

After expiration of the registration period, within which the medicine is permitted for use in Ukraine its further use shall be possible only on conditions of its re-registration.

A decision on rejection of the state registration of the medicine shall be made when the conclusions about its efficacy and safety are not confirmed.

A decision on the state registration of a pharmaceutical may be rejected if such a registration may result in an infringement of valid patent rights through, among others, manufacture, use and sale of medications.

The Ministry of Health of Ukraine or the body authorized by it shall give the applicant a written motivated opinion on rejection of the state registration of the medicine within 10 days. Decision on rejection may be appealed against through the procedure envisaged by the legislation.

The procedure for the state registration (or re-registration) of the medicine and amounts of fees for the state registration (or re-registration) of the medicine shall be established by the Cabinet of Ministers of Ukraine.

Ukraine

Not subject to state registration are the medicinal products, which are prepared in pharmacies under the prescriptions of doctors and at the request of health care settings from active substances and excipients permitted for use.

II. Final provisions

1. This law enters into force as of the date of its publication and shall be applied to the relations which arise after its taking effect.
2. Within the following three months the Cabinet of Ministers of Ukraine shall: harmonise the respective regulations with the provisions of this law; ensure the revision and repeal by the Ministries and other central executive authorities in Ukraine of regulations which do not comply with this Law.

Bahrain



Egypt



Iraq



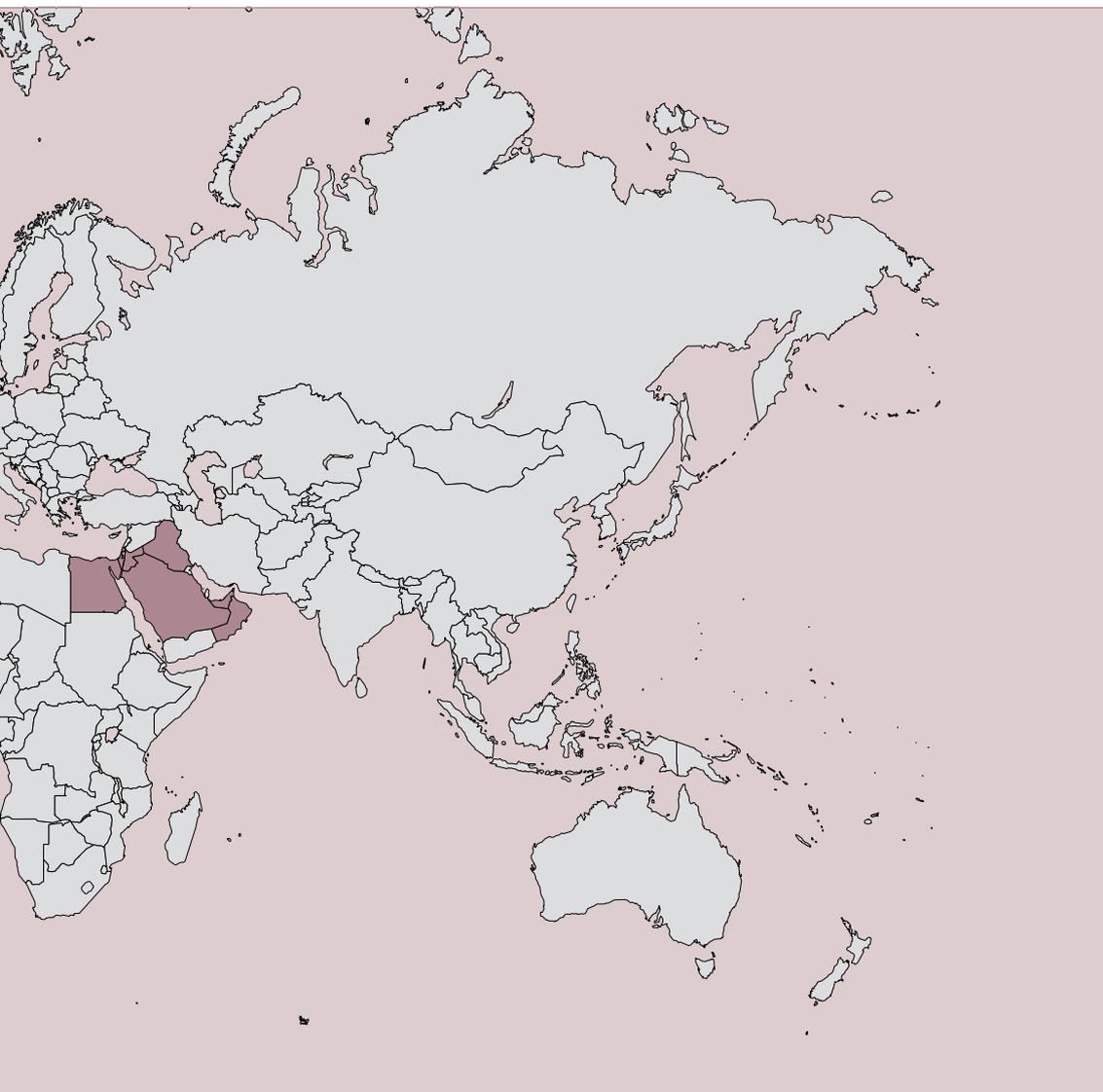
Israel



Jordan



Africa/ Middle East



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Bahrain



Bahrain
5 years



Law No. (7) for the Year 2003 on Trade Secrets

Article (1)

Any natural or legal person is prohibited from disclosing information in his possession if such an information contains the features hereunder:

- A) If the information is confidential. Confidentiality is thereto fulfilled if the information in its final form or its specifics are unknown nor circulated and is not accessible for those who usually deal with such type of information.
- B) If it was of a commercial value due to its confidentiality.
- C) If its confidentiality was dependable on the effective measures undertaken by its legal holder to preserve it. Within the course of implementing provisions of this law, the information stipulated in the features hereinabove are thereto regarded as trade secrets.

Article (2)

Disclosure prohibition of the previously prescribed trade secrets in the above Article extends to include confidential tests and data that were the outcome of notable efforts, and which are submitted to the competent authorities at their request for approval of promoting pharmaceutical or agrichemical products in which new chemical components are used.

The competent authorities shall be obliged to disclose received data or tests of those mentioned in the previous Paragraph until the same is no longer confidential, and prohibit unfair commercial use of the said data or tests by means of not permitting any person without consent of the owner from depending on it to market his own products or pharmaceutical products until after five years consecutive to the date of marketing approval in the Kingdom of Bahrain.



Egypt



Egypt
5 years



Intellectual Property Law No. 82 (2002)

Undisclosed Information – Articles 55-62

Article 56

According to the provisions of this law, protection is extended to the undisclosed information resulting from significant efforts and which was presented to the concerned authorities upon their request to permit the marketing of the pharmaceutical chemical or agricultural products using new chemical entities necessary for needed examinations for its marketing. The concerned authority that receives such information is obliged to protect it from disclosure and prevent its use in illegitimate commercial activities with effect from the date of submitting such information, until the end of its classification as secrecy and for a period not to exceed five years, whichever is shorter.

Disclosure of this information by the concerned authorities to protect the public is not considered a violation to the information rightful owner.

Article 57

The rightful owner of the undisclosed information is obliged to take the necessary procedures to preserve this information and prevent its circulation to non-concerned parties. He is also obligated to regulate the circulation of this information inside the establishment and restricting it to the legal delegates who wrote acknowledgments to preserve it and prevent its disclosure to others. The responsibility of the rightful owner to protect this information shall not end if others violate it, unless he proves that he has exerted sufficient and reasonable effort to protect it.

The secretive feature of this information and all resulting rights to prevent others from infringing it continues, as long as, it remains undisclosed information according to the provisions of article (55) of this law.

The rights of the rightful owner of the undisclosed information rights are restricted to preventing others from infringing it by any of the deeds that contradicts with the honest commercial practices referred to in article (58) of this law. He will also have the right to resort to the courts in case of proving that others commit any of the referred deeds.

The rightful owner or his successor may assign it to others with or without indemnification.

Article 58

The following practices – in particular – shall be considered as contrary to honest commercial practices. Committing it also implies unfair competition.

- (1) Bribing the employees who work in an authority which preserves the undisclosed information, for the purpose of having access to this information.
- (2) Disclosing the information by the employees who know such information through their work.
- (3) If one of the contractors of the “secretive information contracts” disclosed the information that he has access to.
- (4) Getting the information from its storage place by using dishonest ways such as stealing, theft, or any other similar way.
- (5) Obtaining the information by using spying instruments or tools.
- (6) Acquiring the information by using deceptive or fraudulent ways.
- (7) Using the information by others who know that it is secretive but who has gotten it through any of the above mentioned practices.

Disclosing of secretive information, keeping or using it through others who does not have a license from the rightful owner of this information will be considered as a violation to this information.

Egypt

Article 59

The following acts are not contradictory to honest commercial practices:

- (1) Obtaining the information from public available source such as libraries, Patent Office library, government records available to the public, researches studies and published reports.
- (2) Obtaining the information by using personal and independent efforts through inspection, examination and analysis of the market circulated products, which embodies the undisclosed information.
- (3) Getting the information through independent scientific research efforts, innovation, invention, compilation, and development, improvement, and modification efforts that are exerted independently from the rightful owner of the undisclosed information.
- (4) Using or disclosing information that is generally known and is circulated among those who are working in the same industrial field.

Article 60

The rightful owner of or his successor may assign it to others with or without indemnification.

Article 61

Without prejudice to any stronger punishment stated in any other law, a person who knowingly disclosed, kept or used protected information according to the provisions of this law will be subject to a fine of not less than L.E. ten thousand and not to exceed L.E. fifty thousand.

In case of recurrence, the imprisonment punishment will be for a period not less than three years and a fine of not less than L.E. fifty thousand and not to exceed L.E. one hundred thousand.

Article 62

The provisions of articles (34), (36) and (43) will be applicable for this section.

Prime Ministerial Decree No. 2211

Concerning Data Exclusivity Chemical of Chemical Agricultural and Pharmaceutical Products

The Prime Minister after reviewing:

- The constitution,
- Patent and Industrial Designs Law No. 132 of 1949 and its executive regulation,
- The presidential Decree No. 72 of 1995 of joining Arab Republic of Egypt to the World Trade Organization, the agreements that were included in the results of Uruguay Round and the provisions of the Arab Republic of Egypt in the field of trade of products and services which was conducted in Marrakech in April 15, 1994,
- The Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement),
- The Prime Minister Decree No. 547 of 2000 regarding EMR,
- And according to what was introduced by the Minister of Economy and External Trade.

The following is decided:

- (1) The provisions of this decree shall be effective for the confidential data and information which were the results of good efforts, and which are to be submitted to the concerned ministry upon its request for approving the marketing of chemical pharmaceutical products or chemical agricultural products which are used as a new chemical data, whenever these information and data are necessary for obtaining a marketing approval.
- (2) The concerned Ministry for the protection of data and information referred to in Article 1 is committed to protect it against any unfair commercial use and to keep it undisclosed, unless it was necessary, in order to protect the public or accompanied with adequate measurements to guarantee its protection from unfair commercial use.

The provisions of the above paragraph shall be effective starting from the date on which the information and data referred to are submitted to the concerned Ministry, and until the secretive feature of these information is terminated.

- (3) What is meant by the concerned Ministry applying the provisions of this decree is the Ministry of Health with regard to Pharmaceutical chemical products and the Ministry of Agriculture with regard to Agricultural chemical products.
- (4) The provision of this decree shall not be applicable for products and materials which its the legal protection period is expired, including materials and products listed in the local and foreign pharmacopoeia.
- (5) This decree is to be published in the official gazette and be effective from the second day following its publication date.

Iraq

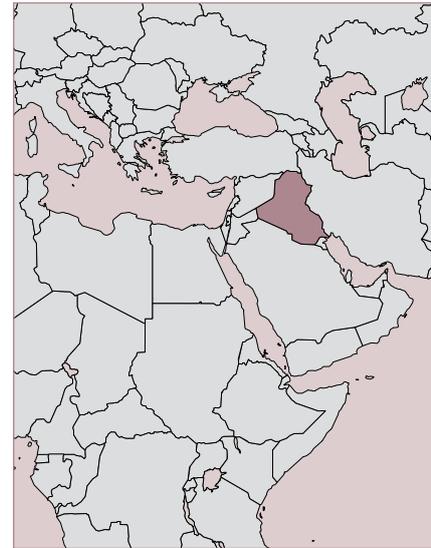
Coalition Provisional Authority Order Number 81, “the Patent and Industrial Designs Laws and Regulations (No. 65 of 1970)” was renamed as the “Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law”

Applies only to approvals that were obtained on or after April 26, 2004

31) Chapter Three bis, Article 2 is added to read as follows:

“If the Minister requires the submission of data pertaining to secret tests, or any data which has been derived as a result of considerable efforts in order to approve the marketing of pharmaceuticals or chemical agricultural products which contain new chemical substances, then the Minister shall comply with the following:

- a) Protection of such data from unclassified commercial use through prohibiting any other person who did not obtain the consent of the submitter to rely on it for marketing that other person’s pharmaceuticals and products except after the lapse of five years as of the date of obtaining the submitter of such data the approval to market those products; and
- b) The protection of this data from disclosure with the exception of the following:
 - i) should disclosure be necessary for the protection of the public; or
 - ii) should the Minister realize the necessary precautions to guarantee unclassified commercial use of such data.”



Iraq
5 years

Israel



Israel
5 or 5^{1/2} years⁷



Chapter I: Health Amendment of the Pharmacists' Ordinance Commencement and Effect

For products registered in Israel after January 1, 2005

41. (A) The following shall be added after Art. 47C. of the pharmacists' Ordinance [New Version], 5741-1981 (in this chapter – Pharmacists' Ordinance):
- 47D. (A) In this article
- (B) The Director shall not issue a permit for the marketing in Israel a New Medical Preparation, whose marketing needs a permit according to the provisions of Reg. 14 of the Pharmacists Regulations (Preparations), 5746-1986, unless one of the following exists:
- (1) The applicant for the registration of the New Medical Preparation has received the consent of the proprietor of the registration of the Original Preparation for the use of the Confidential Information.
 - (2) At least five years have passed from the day the Original Preparation was first registered in the Preparations' Register or five years and six months have passed from the day a preparation containing the New Chemical Entity of the Original Preparation was first registered in a Recognized Country, whichever precedes.
 - (3) The Applicant for the registration of the medical preparation has provided complete data, satisfactory by the Directors' discretion, in order to prove the safety, efficacy and quality of the New Medical Preparation.
 - (4) A need for the use of the New Medical Preparation exists due to one of the following:
 - (a) One of the conditions mentioned in Art. 20(1) of the People's Health Ordinance exists.
 - (b) A threat to a severe and present danger to the public's health exists, by proclamation of the Minister Notified in Official Publications (Reshumot).

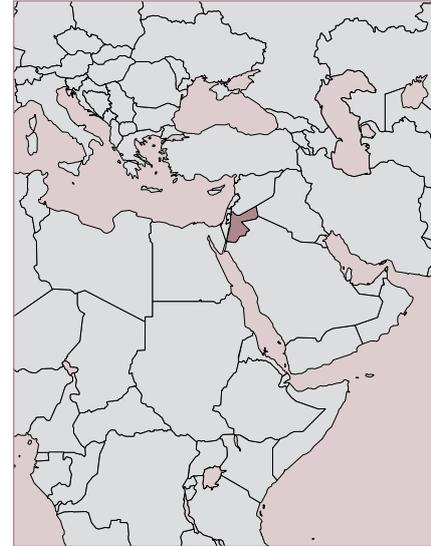
⁷ USTR-Government of Israel Agreement on Pharmaceutical IP – 6 or 6 ½ years. According to the USTR-GOI agreement on data protection, Israel is obligated to enact legislation implementing the following policy: "the term of protection available shall expire no later than six and one half (6.5) years after the date the said medical preparation containing a New Chemical Entity first received marketing approval in any recognized country. Or if the first worldwide filing for the application for marketing approval of the medical preparation containing a New Chemical Entity occurs in Israel, six (6) years after the date that marketing approval is granted in Israel for that medical preparation containing a New Chemical Entity".

Jordan

Article (8) – Trade Secrets and Unfair Competition Law, No. 15 (2000)

If any official competent authority requires the submission of undisclosed tests, or other data which are a result of considerable effort, in order to approve the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, such authority shall observe the following:

- a) Protect such data from unfair commercial use, by preventing any person not having the applicant's consent from using the data to market such pharmaceuticals and his own products, only after the lapse of five years from the date the applicant of such data obtained the approval to market his products.
- b) Protect such data from disclosure except in the following
 1. Where it is necessary to protect the public
 2. Where the competent authority took the necessary steps to ensure that the data are protected against unfair commercial use.



Jordan
5 years

Morocco



Morocco
5 years



Article 15.10: Measures Related To Certain Regulated Products

1. If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of:
 - (a) safety and efficacy data, or
 - (b) evidence of prior approval of the product in another territory that requires such information,

The Party shall not permit third persons not having the consent of the person providing the information to market a product on the basis of the approval granted to the person submitting that information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party's territory. For purposes of this paragraph, a new product is one that contains a new chemical entity that has not been previously approved in the Party's territory.

2. If a Party requires the submission of:
 - (a) new clinical information that is essential to the approval of a pharmaceutical product (other than information related to bioequivalency), or
 - (b) evidence of prior approval of the product in another territory that requires such new information,

the Party shall not permit third persons not having the consent of the person providing the information to market a pharmaceutical product on the basis of such new information or the approval granted to the person submitting such information for at least three years from the date of approval in the Party. A Party may limit such protection to new clinical information the origination of which involves considerable effort.

3. With respect to patents covering pharmaceutical products, each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.
4. With respect to any pharmaceutical product that is subject to a patent, and where a Party permits authorizations to be granted or applications to be made to market a pharmaceutical product based on information previously submitted concerning the safety and efficacy of a product, including evidence of prior marketing approval by persons other than the person that previously submitted such information, that Party:
 - (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent during the term of that patent, unless by consent or with the acquiescence of the patent owner, and
 - (b) if it allows applications to be made to market a product during the term of a patent covering that product, shall provide that the patent owner shall be notified of the identity of any such other person who requests marketing approval to enter the market during the term of a patent notified to or identified by the approving authority as covering that product.

Oman

Sultan Decree No. 38/2000, The Law of Trademarks, Trade Data, Undisclosed Trade Information and Protection from Unfair Competition

Article 34 – Natural and Juridical persons are prohibited from disclosure of commercial secrets, which they have in their possession in a manner, which is incompatible with fair conduct of trade. A trade or industrial activity is considered a secret if its nature is unknown, if its commercial value stems from being a secret, if reasonable measures were taken to keep it a secret or if it is not easy for a person with ordinary knowledge in this field to achieve this knowledge.

It is considered as divagation of commercial data, making use of the data of tests or other secret data which is filed at the competent authorities in order to obtain the marketing authorization needed for the pharmaceutical preparations or agricultural products containing new chemicals, if considerable effort has been made in order to attain these products.

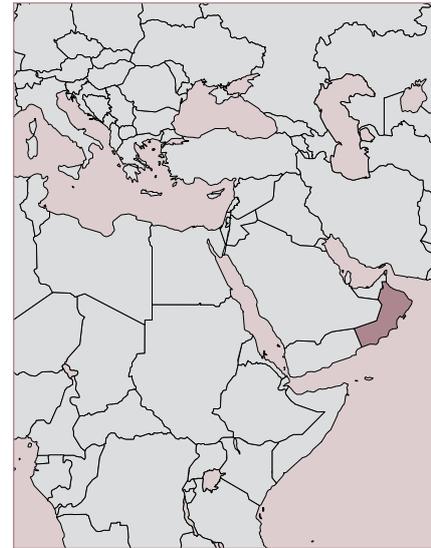
Law on Industrial Property and their Enforcement, Royal Decree 67/2008

Regulations under the Law on Industrial Property Rights and their Enforcement for the Sultanate of Oman

Article 89 – Measures Related to Pharmaceutical and Agricultural Chemical Products

Article 64(3)(A)(1) of the Act shall be construed to provide that:

1. unfair commercial use include reliance by a governmental authority upon undisclosed test or other data concerning safety and efficacy submitted to it as a condition of marketing approval, without consent of the person submitting the data, within the applicable minimum 5 or 10 year period, in the approval of a same or similar product.
2. the applicable minimum 5 or 10 year period begins on the marketing approval date in Oman of the pharmaceutical or agricultural chemical product that data was originally submitted to support.
3. unfair commercial also includes reliance by a government entity on undisclosed test or other data submitted to it as a condition of marketing approval for a new use of an agricultural chemical product which does not contain a chemical entity which has not been previously approved in Oman, in the approval of a same or similar product based on that data within 10 years from the date of the original marketing approval of the agricultural chemical product in Oman.



Oman
5 years

Saudi Arabia



Saudi Arabia
5 years



Decision No. 3218: Regulations for the protection of Confidential Commercial Information, later amended by Decision No. 4319 of 2005

Applies to products approved in Saudi Arabia on or after May 4, 2005

Article 5 – Where an official competent authority requires the submission of information about secret tests or any data obtained as a result of substantial efforts, as a precondition for approving the marketing of drugs or chemical agricultural products in which new chemical substances are used, the said authority shall undertake to protect such information against unfair commercial use, for a minimum period of five years from the date of obtaining the approval.

Article 6 – The competent registration authority – during the protection term of commercial secrets – may permit third parties to use the undisclosed data of secret tests submitted by another application in the following cases:

- (1) If the product first registered in the Kingdom has not been subject of trading within a reasonable period of time determined by the registration authority, after approving its marketing.
- (2) If this is required by a pressing necessity determined by the competent authority to protect the public.

Article 8 – Any person harmed as a result of violating the provisions of these Regulations may file a law suit before the competent judicial authority to claim compensation for damages sustained.

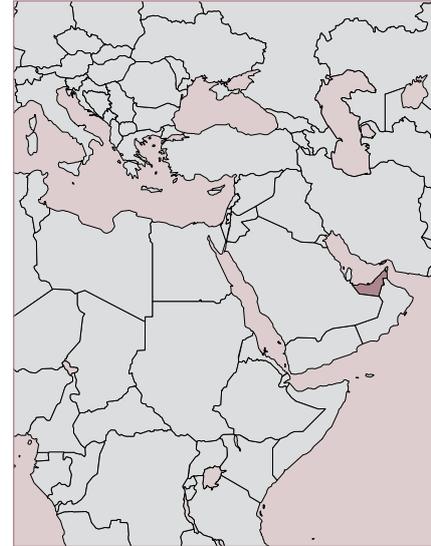
United Arab Emirates

Ministers of Health and of Finance & Industry

Decree No. 404/2000:

The Ministry of Health shall issue a Ministerial Decree defining protection for secret information of pharmaceutical products as follows:

With respect to applications submitted for marketing approval after 1 January 2000, the period of protection for data secrecy shall be the period of validity for the patent over the original drug in the country of origin.



United Arab
Emirates
Not specified

Australia



China



Hong Kong



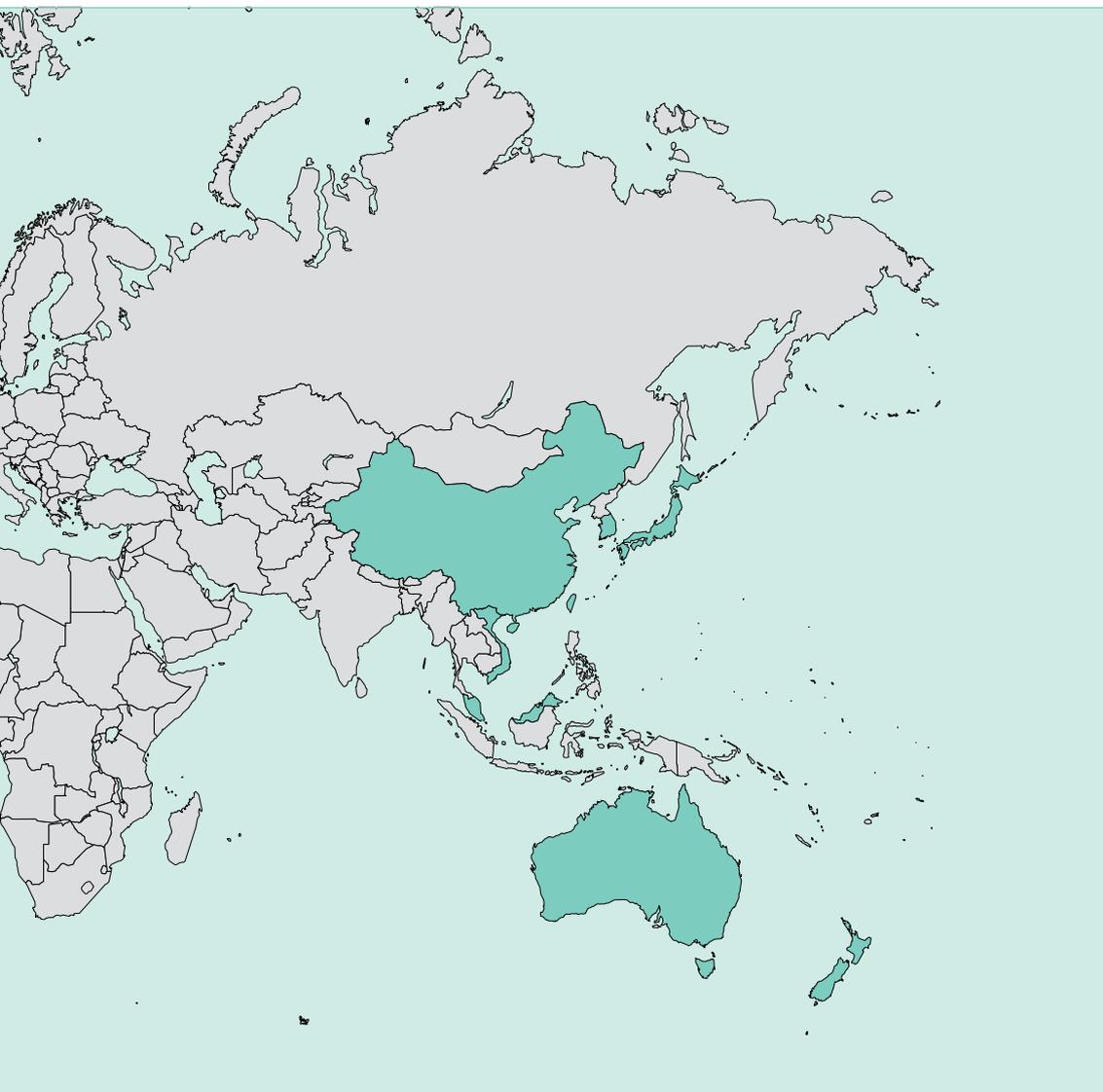
Japan



Malaysia



Asia/Pacific Rim



New Zealand



Republic of Korea



Singapore



Taiwan



Vietnam

Australia	66
China	67
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Japan	70
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Singapore	77
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Vietnam	79

Australia



Australia
5 years



Data Exclusivity Provision of the Therapeutic Goods Act (Cth) 1989 (Australia)

25A When the Secretary must not use protected information

- (1) When evaluating therapeutic goods for registration, the Secretary must not use information about other therapeutic goods that is protected information.
- (2) Information is *protected information* if:
 - (a) the information was given to the Secretary in relation to an application to register therapeutic goods (the *new goods*):
 - (i) not being therapeutic devices; and
 - (ii) consisting of, or containing, an active component; and
 - (b) the information is about the active component and is not available to the public; and
 - (c) when the application to register the new goods was lodged:
 - (i) no other therapeutic goods consisting of, or containing, that active component were included in the Register; and
 - (ii) no such therapeutic goods had been included in the Register at any time before then; and
 - (d) the new goods became registered on or after the commencement of this subsection; and
 - (e) 5 years have not passed since the day the new goods became registered; and
 - (f) the person in relation to whom the new goods are registered has not given the Secretary permission in writing for the Secretary to use the information.
- (3) For the purposes of subsection (2), an *active component*, in relation to therapeutic goods, is a substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods.
- (4) The use of protected information contrary to subsection (1) does not render the Commonwealth, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage or injury of any kind suffered by the person as a result of, or arising out of, the use of that information.

China

Report of Working Party on the Accession of China to the WTO (WT/ACC/CHN/49)

284 – The representative of China further confirmed that China would, in compliance with Article 39.3 of the TRIPS Agreement, provide effective protection against unfair commercial use of undisclosed test or other data submitted to authorities in China as required in support of applications for marketing approval of pharmaceutical or of agricultural chemical products which utilized new chemical entities, except where the disclosure of such data was necessary to protect the public, or where steps were taken to ensure that the data are protected against unfair commercial use. This protection would include introduction and enactment of laws and regulations to make sure that no person, other than the person who submitted such data, could, without the permission of the person who submitted the data, rely on such data in support of an application for product approval for a period of at least six years from the date on which China granted marketing approval to the person submitting the data. During this period, any second applicant for market authorization would only be granted market authorization if he submits his own data. This protection of data would be available to all pharmaceutical and agricultural products which utilize new chemical entities, irrespective of whether they were patent-protected or not. The Working Party took note of these commitments.

Regulations for Implementation of the Drug Administration Law of the People's Republic of China (Decree of the State Council No. 360)

Article 35 – The State protects undisclosed data of drug study and others which are independently acquired and submitted by drug manufacturers or sellers to obtain production or marketing approval of the drugs in question which contain new chemical entities. No one may make unfair commercial use of the said data.

Within six years from the date a drug manufacturer or seller obtains the approval documents for producing or marketing a drug containing new chemical entities, if any other applicant uses the data mentioned in the preceding paragraph to apply for approval for production or marketing of the drug in question without permission of the original applicant who has obtained the approval, no approval may be given to any other applicant by the drug regulatory department except that the data submitted are acquired independently.

No drug regulatory department may disclose the data set forth in the first paragraph of this Article except

- (1) for the need of public interests; or
- (2) where steps are taken to ensure that the data are protected against unfair commercial use.



China
6 years

Hong Kong

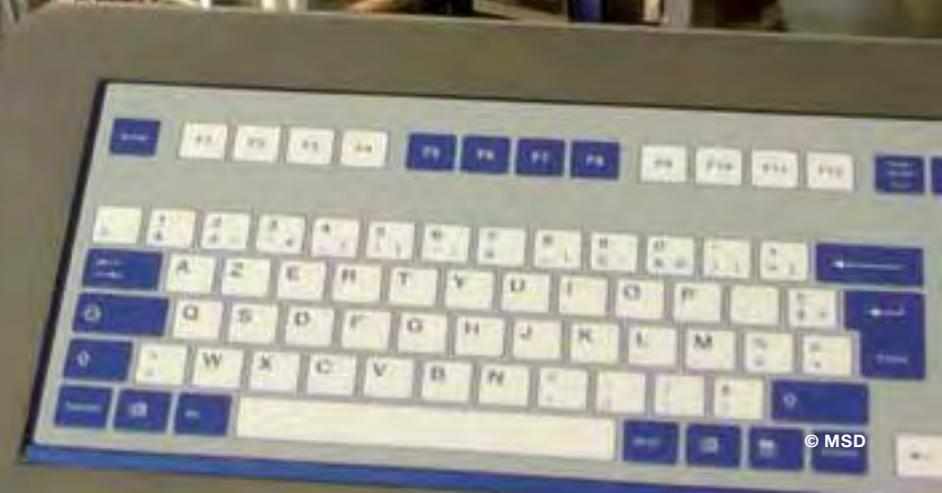
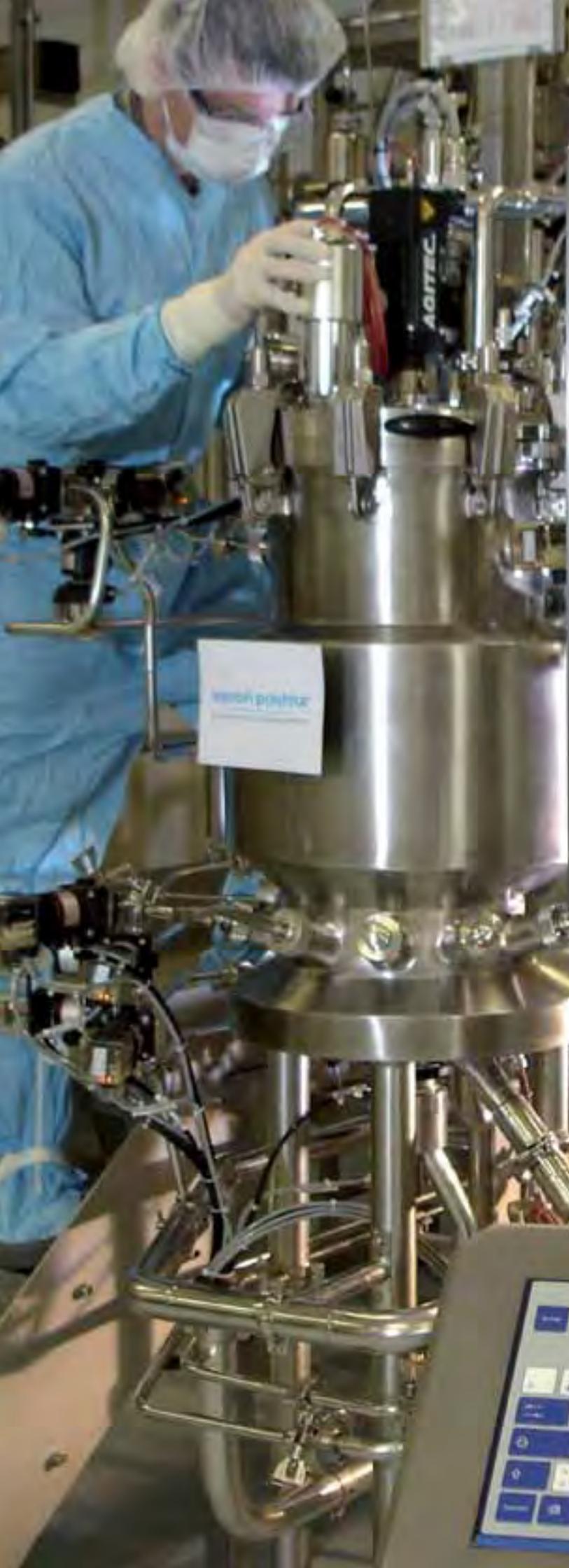


Pharmacy and Poisons Regulations, Ordinance Cap 138

In Hong Kong, pharmaceutical products must be registered with the Department of Health under the Pharmacy and Poisons Ordinance (Cap.138) before sale. For a product to be registered, the manufacturer concerned is required by Cap.138 to provide the necessary scientific documentation to substantiate the safety, efficacy and quality of the product. If the applicant does not provide his own documentation, the Department of Health will not refer to other sources. Undisclosed documentation submitted by another manufacturer to the Department of Health in support of the application for registration of another pharmaceutical product is never referred to, nor is it relied on, by the Government examiners so as to protect data contained therein against unfair commercial use. For generic products, clinical data are not required if the original innovative product has been registered for 5 years or more.

Hong Kong
Not specified







Japan
8 years⁸



Medical Devices, Article 14-4

1. Persons who have received marketing approvals pursuant to the provisions of Article 14 for the drugs or medical device indicated in the following items shall apply within the period specified in each item for the drug or medical device concerned for a reexamination by the Minister.
 - (1) Drugs or medical devices which are designated by the Minister at the time of approval as drugs for which the active ingredients and quantities, dosage and administration, indications, etc. or as medical devices which are designated by the Minister at the time of approval as drugs for which the active ingredients and quantities, dosage and administration indications, etc. or as medical devices for which the structure, method for use, indications or performance are clearly different from those of drugs or medical devices that have already been approved for marketing (hereinafter referred to as “new drugs” or “new medical devices”). Within 3 months (referred to as the application period in the following items) from the date on which the period specified in the following items (hereinafter referred to as the “reexamination period”) has passed.
 - a. A period designated by the Minister of at least 6 years but not exceeding 10 years from the date of the marketing approval for orphan drugs or other drugs specified by MHLW Ordinance that the Minister designates after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council. (A period designated by the Minister of at least 4 years but not exceeding 7 years for orphan medical devices or other medical devices specified by MHLW Ordinance).
 - b. A period designated by the Minister not exceeding 6 years (4 years for medical devices) from the date of marketing approval for drugs or medical devices for which only the indications clearly differ from those of drugs or medical devices which have already been approved for marketing (excluding drugs or medical devices in (a) above) or other drugs specified by MHLW Ordinance which the minister designates after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council.
 - c. Six years from the date of marketing approval for drugs or 4 years for medical devices other than those specified in (a) or (b) above.
 - (2) Drugs or medical devices which are designated by the Minister at the time of marketing approval as drugs for which the active ingredients and quantities, dosage and administration, indications, etc. or medical devices for which the structure, method of use, indications or performance are the same as those of new drugs or new medical devices excluding those for which the reexamination period has passed from the date of marketing approval (the extended period) when the reexamination period is extended pursuant to the provisions of the following article): A period designated by the Minister that corresponds to the application period (the application period specified on the basis on the period after the extension when the reexamination period is extended pursuant to the provisions of the following paragraph).
2. When the Minister confirms that it is especially necessary to perform proper reexaminations of new drugs, the Minister shall be able to extend the reexamination period to a period not exceeding 10 years, (7 years for new medical devices) from the date of marketing approval after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

⁸ “8 years re-examination period is assigned for medicinal products with new active ingredients based on PFSB (Pharmaceutical and Food Safety Bureau) Notification No. 0401001, 1st April 2007.”

Japan

3. These reexaminations of the Minister shall be performed by confirming that the drugs or medical devices specified in any of the items of Paragraph 1 do not conform to Items (3(a) to (c) of Paragraph 2 of Article 14 on the basis of findings obtained in the reexamination.
4. The application specified in Paragraph 1 shall be made by means of a application form with data concerning the results of use of the drug or medical device and other data specified by MHLW Ordinance, the data concerned must be collected and complied in accordance with standards specified by the Minister.
5. The confirmation pursuant to the provisions of Paragraph 3 shall be performed by means of an examination of the quality, efficacy and safety of the drug or medical device concerned based on the contents of the application for the drug or medical device in each item of Paragraph 1 and the data and the data specified in the first part of the preceding by MHLW ordinance pursuant to the provisions of the last part of the preceding paragraph, a paper examination or an on-site examination shall be performed beforehand to determine if the data for the drug concerned complies with that specified in the last part of the preceding paragraph.
6. Persons who have received approval to market drugs or medical devices specified in the items in Paragraph 1 as indicated in Article 14, shall investigate the results of use, etc. for the drug or medical device concerned as specified by MHLW Ordinance and shall report these results to the Minister.
7. Persons who should receive reexaminations for drugs or medical devices specified in MHLW Ordinance pursuant to the provisions of the last part of Paragraph 4, persons entrusted with the collection or completion of data pursuant to the provisions of the last part of the same paragraph or their executive or employees shall not reveal secret concerning the collection or compilation of data or the secret of persons they have become acquainted with in connection with their work unless they have a valid reason for doing so. This shall also apply in person formerly in such positions.

Malaysia



Malaysia
5 years



Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984

- 1.1 The Directive of Data Exclusivity (DE) is issued by the Director of Pharmaceutical Services under regulation 29 of the Control of Drugs and Cosmetics Regulations 1984.
- 1.2 The Directive is to protect the undisclosed unpublished and non-public domain pharmaceutical test data, the origination of which involves a considerable effort, submitted as required to the Director of Pharmaceutical Services for the purpose of scientific assessment in consideration of the:
 - i) Quality, Safety and Efficacy of any new drug product containing a New Chemical Entity
 - ii) Safety and Efficacy for a second indication of a registered drug product as a condition for
 - a) Registration of any new drug product containing a New Chemical Entity, or
 - b) Approval for a Second Indication of a registered drug product

Application and Date of Coming Into Force

- i) This Directive is applicable to:
 - a) New drug product containing a New Chemical Entity; and
 - b) Second indication of a registered drug product
- ii) This directive shall come into force on 01 March 2011

Definitions

- 3.1 New drug product containing any New Chemical Entity means 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.
- 3.2 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.
- 3.3 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.
- 4.1 Any person may apply for Data Exclusivity. Such application shall be made upon submission of documents to the Director of Pharmaceutical Services for the 1) registration of new drug product containing a New Chemical Entity; or ii) approval for Second indication of a registered drug product.
- 4.2 An application for Data Exclusivity shall only be considered if the application in Malaysia for:
 - i) 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.
 - ii) 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.

Malaysia

4.3 Before the Data Exclusivity is granted:

- i) 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
- ii) the applicant for a Second Indication of a registered drug product shall provide to the Director of Pharmaceutical, the reports of new clinical investigations other than bioavailability studies, conducted in relation to the second indication and the origination of which ahs involved considerable effort.

4.4. 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.

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

- i) five (5) years for new drug product containing a New Chemical Entity and
- ii) 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.

4.6 Calculation of the period of Data Exclusivity

- i) 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.
- ii) 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.

4.7 Consideration of other applications upon the grant of Data Exclusivity

For all 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:

- i) 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 of the drug product submitted for registration; OR
- ii) The applicant has obtained consent in writing for right of reference or use of the test data from a person authorized by the owner of the registered ne drug product containing a New Chemical Entity.

Non Application of Data Exclusivity

5. Nothing in the Data Exclusivity shall:

- i) apply to situations where compulsory licenses have been issued or the implantation of any other measures consistent with the need to protect public health and ensure access to medicines for all;
- ii) 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.

New Zealand



New Zealand
5 years



Medicines Act 1981 No. 118

23B Protection of confidential supporting information about innovative medicines

Where the Minister receives, or received not more than 5 years before the commencement date, an innovative medicine application and confidential supporting information, the Minister, during the protected period in relation to that confidential supporting information,

- (a) Shall take reasonable steps to ensure that that confidential supporting information is kept confidential to the Minister; and
- (b) Shall not use that confidential supporting information for the purposes of determining whether to grant any other application.

23C Circumstances where protection under section 23B does not apply

- (1) Notwithstanding section 23B of this Act, the Minister may, during the protected period in relation to confidential supporting information,
 - (a) Disclose that confidential supporting information, or use that confidential supporting information for the purposes of determining whether to grant any application other than the application to which it relates or related, as the case may be,
 - (i) With the consent of the applicant who made the application to which the confidential supporting information relates or related; or
 - (ii) If that disclosure or use is, in the opinion of the Minister, necessary to protect the health or safety of members of the public; or
 - (b) If, in the opinion of the Minister, the relevant committee, adviser, Government department, statutory body, or person will take reasonable steps to ensure the confidential supporting information is kept confidential, disclose that confidential supporting information to—
 - (i) An advisory or technical committee appointed under section 8 of this Act; or
 - (ii) The Medicines Classifications Committee appointed under section 9 of this Act; or
 - (iii) The Medicines Review Committee established under section 10 of this Act; or
 - (iv) Any adviser for the purpose of obtaining advice about the medicine to which the confidential supporting information relates; or
 - (v) A Government department or statutory body for the purposes of the Government department or statutory body; or
 - (c) Disclose that confidential supporting information to any one or more of the following—
 - (i) The World Health Organisation;
 - (ii) The Food and Agriculture Organisation;
 - (iii) Any regulatory agency of a WTO Country;
 - (iv) Any person or organisation, or a person or organisation within a class or classes of persons or organisations, approved by regulations made under this Act.

- (2) The power to grant consent under subsection (1)(a)(i) of this section may be exercised by a person other than the applicant referred to in that subsection if—
- (a) That applicant—
 - (i) Has notified the Minister in writing that that other person may grant that consent; and
 - (ii) Has not notified the Minister in writing that that person's authority to grant that consent has been withdrawn; or
 - (b) That applicant's rights in respect of the relevant confidential supporting information have been transferred to that person and the applicant or that other person has notified the Minister in writing of the transfer.

Republic of Korea



Republic
of Korea
4 or 6 years



Pharmaceutical Affairs Law (PAL)

Article 32

Of the drugs for which products licenses were issued in accordance with the provisions of Paragraph 2 and 3, Article 31, those products falling under the provisions of Paragraph 8, Article 31 shall be subject to re-examination by the Commissioner of the KFDA within 3 months after 4 or 6 years from the date of issuance of the license, depending on the product.

The method, procedure and timing of re-examination pursuant to Paragraph 1 shall be determined by Decree of the Minister of Health and Welfare.

Ministerial Decree to PAL

Article 35

The period for re-examination of the products that are subject to re-examination pursuant to Paragraph 1, Article 32 of the PAL or Paragraph 4, Article 42 of the PAL is as follows:

1. Items to be re-examined six (6) years after the date of license:
 - a) New drugs.
 - b) Ethical drugs different from already licensed drugs in terms of active ingredients or composition ratios.
 - c) Ethical drugs different from already licensed ones in the route of administration, while containing the same active ingredients.
2. Items to be re-examined four (4) years after the date of license:
 - a) Ethical drugs which are identical to already licensed drugs in terms of active ingredients and route of administration but distinctively different in added indications.
 - b) Other drugs whose re-examination is deemed necessary by the Commissioner of the KFDA.

KFDA Regulations regarding the Licensing, Report and Examination of Drug Products

Article 25

Examination of safety and efficacy pursuant to Item 1, Paragraph 1, Article 24 and Article 29 of the Ministerial Decree to the PAL shall be performed with respect to drugs that have received a license or amended license or that have filed a report or amended report, unless falling under one of the following:

1. A product that is identical in the type of active ingredient, size and quantity (concentration in the case of liquids), dosage form, indication, administration and dosage with a product that has already been licensed or reported.
2. Despite the proviso to Paragraph 1, a drug that falls under one of the following must be examined for safety and efficacy by submitting data pursuant to Article 5 of 8:
8. A product that is identical to a drug that has been designated as subject to re-examination pursuant to the provisions of Paragraph 1, Article 32 of the PAL, Paragraph 4, Article 42 of the PAL or Article 57 of the Act on Management of Narcotic Drugs.

Article 27

If falling under Item 8, Paragraph 2, Article 25, data which is not the same as the data submitted for the original approval must be submitted, unless falling under one of the following:

1. Use of the data is permitted by the party that first received a license or the original developer;
2. Drugs falling under Item 8, Paragraph 2, Article 25 that apply on condition that they will receive a license after the expiration of the re-examination period.

Singapore

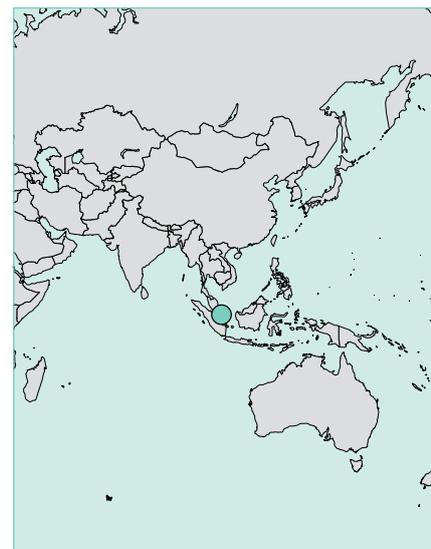
Medicines Act (Chapter 176)

No product licence to be granted on basis of previous grant 19D.

- (1) Where
- (a) information has been provided by an applicant for a product licence to the licensing authority relating to the safety or efficacy of a medicinal product in support of such application; and
 - (b) a product licence has been granted in respect of that medicinal product (referred to in this section as the earlier licence),

the licensing authority may not, for a period of 5 years from the date of such grant, grant a product licence to another person in respect of that or a similar medicinal product on the basis of the grant of the earlier licence unless the holder of the earlier licence has given his consent to the grant on that basis.

- (2) This section applies where the earlier licence is granted
- (a) on or after the date of commencement of the Medicines (Amendment) Act 2004; or
 - (b) at any time between the date that is before the date of commencement but no earlier than 5 years before that date, and that date.



Singapore
5 years

Taiwan



Taiwan
5 years



Pharmaceutical Affairs Law, Article 40

February 5, 2005

Article 40-1

For the purpose of protecting public interest, the central health competent authority may, where necessary, announce the relevant information of a drug's ingredients, product insert, and so on obtained and kept by it due to the application submitted by a pharmaceutical firm for manufacture or import of such drug; provided that the central competent authority shall keep in confidence any information which is the pharmaceutical firm's trade secret submitted for examination and registration of a new drug.

With respect to the scope and method of such disclosure, as referred to in the preceding paragraph, the central health authority shall enact the regulations to govern these matters.

Article 40-2

While granting the certificate of pharmaceutical product, the central health competent authority shall announce the disclosed patent number or patent application number provided by the applicant.

Within 5 years from the date of issuance of the certificate of pharmaceutical product for new drugs with new ingredients, other pharmaceutical firms shall not make reference to any previous application materials to apply for examination and registration without the consent of the holder of the certificate of pharmaceutical product.

Three years after the date of issuance of the certificate of pharmaceutical product for new drugs with new ingredients, other pharmaceutical firms may submit the applications for examination and registration of drugs with the same ingredients, dosage forms, same volumes and same units in accordance with this Law and relevant regulations relating to the examination and registration of drugs and the certificate of pharmaceutical product may be issued to those qualified applicants on the next day after expiration of the five years of the certificate of pharmaceutical product for new drugs with new ingredients.

With respect to new drugs with new ingredients, for which a market approval has already been obtained in a foreign country, provisions prescribed under the Second Paragraph of this Article could be applied to mutants only when the application for examination and registration of such new drugs has been filed with the central health authority within three years from the issuance date of such market approval.

The protection offered by this Article does not apply to data collected by non-patent holders for educational and clinical research purposes.

Vietnam

National Assembly of the Socialist Republic of Vietnam

Intellectual Property Law

Article 128 – Obligations to maintain secrecy of data of tests

1. Where the laws require an applicant for a business license or a permit for circulation of pharmaceutical products or agricultural chemical products to submit test results or any other data of the trade secret the origination of which involves considerable effort or expenses, and where the applicant requests that such information be kept secret, the authority shall have obligation to take necessary protective measures so that such data shall neither be used for unfair commercial purposes nor disclosed, except where the disclosure thereof is necessary to protect the public.
2. From the submission of the secret data in an application to the authority as provided for in paragraph (1) of this Article to the end of the 5-year period counted from the date on which a license or permit is granted to the applicant, the authority shall not grant such a license to any *subsequent* applicant in whose application the secret data mentioned above are used without consent of the previous applicant, except in the case as provided for in subparagraph (d) paragraph (3) of Article 125 of this Law.



Vietnam
5 years

The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing the research-based pharmaceutical, biotech and vaccine sectors. Its members comprise 26 leading international companies and 44 national and regional industry associations covering developed and developing countries. The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal (www.ifpma.org/clinicaltrials) and IFPMA activities in Health Partnerships (www.ifpma.org) help make the industry's activities more transparent. The IFPMA strengthens patient safety by improving risk assessment of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).



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