EMBASSY OF INDIA

SANTIAGO

CHILE

PHARMACEUTICAL MARKET

LEGAL FRAMEWORK

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on behalf of

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Economic Diplomacy Division

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I N D E X

This survey aims to provide relevant information on the legal framework applicable to the pharmaceutical market in Chile, so that Indian medicament exporters may get a deep understanding of it and take it into account in developing and executing a successful market entry into Chile.

1. Current legislation and regulation

Chilean pharmaceutical market is ruled by the Health Code (Decree with the Force of Law DFL 725), enacted in 1967, and its further modifications. This legal text settles the general rules for health promotion, protection and recovery of Chilean inhabitants. Specifically, its section called "Book 4" gathers the general provisions concerning pharmaceutical and medical-usage products, as same as food and cosmetics.

The Health Code acts as an "umbrella" under which are several laws concerning different aspects of the pharmaceutical sector. There are also several regulations (mainly issued by the Ministry of Health) that rule the practical way the law should be implemented.

Regulations on the National System of Pharmaceutical Products for Human Usage ("Reglamento del Sistema Nacional de Control de los Productos Farmacéuticos de Uso Humano")[1] – known as Decree Law 3/2010 - contains the main rules and procedures and many of them will be explained below.

In addition, other legal texts are applicable to the pharmaceutical market - such as laws and regulations related to intellectual property, customs and government purchases - which will also be addressed below.

1.1 Market Entry

1.1.1 Pharmaceutical Product Registration

Prior to their sale, distribution and usage, pharmaceutical products should be registered upon the Institute of Public Health ("Instituto de Salud Pública" or its acronym ISP), with a special registry, namely, the Sanitary Registry of Pharmaceutical Products ("Registro Sanitario de Productos Farmacéuticos").

1 To see the full text (in Spanish) click on this link: www.leychile.cl/Navegar?idNorma=1026879

This Sanitary Registry process consists on a systematic evaluation of the pharmaceutic, pharmacologic, toxicology and clinic characteristics of products, in order to verify their quality, safety and efficacy.

The registration process should be conducted according to a pre-defined procedure, which considers the submission of administrative and technical information, as same as of pharmaceutical quality, safety and efficacy. It also involves the payment of a fee. Information and documents can be submitted in paper or using the ISP´s online system called GICONA.

The application to the Sanitary Registry could be submitted by any person, natural or legal entity, Chilean or foreign, with residence or representation in Chile.

Apart of the regular Sanitary Register request procedure, there are two other ones: simplified and abbreviated. Each has their own instructions, application forms and fees[2].

The simplified registration procedure – which requires the submission of less documents and information – is applicable in the following cases:

- Products containing the same active ingredients, in the same quantity and using the same route of administration than already registered products (not benefiting of exclusivity period).
- Products, which active ingredients are sufficiently known and which efficacy, safety of usage and adverse reactions are described in the scientific literature.
- Products that are pharmaceutically equivalent to another already registered, which active ingredients are part of a list of ingredients having specific norms to follow to demonstrate their therapeutic equivalence (bioequivalence).
- Products manufactured in Chile for the sole purpose to be exported.

The abbreviated procedure is used in few cases, when medicines are to be used in programs implemented by the Ministry of Health or to be included in the "Formulario Nacional de Medicamentos"[3].

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2 Find the complete procedure for submitting sanitary registration applications by clicking on these links:
Ordinary Procedure:
www.ispch.cl/sites/default/files/instructivo_requisitos_solicitud_rgistro_ordinario_sro_02_12_2014%20%20INCLUYE%20NORMA%20170%20DE%20BIOTECNOL..pdf
Simplified Procedure:
www.ispch.cl/sites/default/files/prestacion/2012/03/instructivo_solicitud_registro_productos_simplificados_11_02_13.pdf

3 "The Formulario Nacional de Medicamentos" is a list of pharmaceutical products defined by law and considered as essential vis-à-vis the Chilean epidemiological context.

Sanitary registration ranges from USD 1.000 to 1.500, depending on the type of product and procedure. The registration process for a new pharmaceutical product takes about 6 to 10 months, under the regular procedure. Under the simplified one, it lasts around 4 to 7 months.

It should be noted that approvals granted by international agencies (i.e. FDA or EMEA) are favourable background for the registration process, but they do not eliminate or bypass it.

Besides, the sanitary registration is independent of the patent registration (see Section 1.1.4) and/or other aspects inherent to a pharmaceutical product (presentation, formulas, production processes, etc.). Patent information concerning a new drug is neither requested nor verified when sanitary registration is granted.

The Institute of Public Health (ISP) keeps an updated list of all the pharmaceutical products already registered, which can be accessed online by any person.[4]

1.1.2 Bioequivalent products

In 2005, the Ministry of Health issued the first list of active ingredients compelled to demonstrate their bioequivalence. From then on, several new active ingredients have been constantly added to the list[5].

Up to now, only medicines under the form of solid for oral intake and aqueous solutions have been included in the mentioned list.

According to current Chilean regulations, to be considered as therapeutically bioequivalent compared to a reference medicine, a drug must:

- Have a sanitary registration in force.
- Comply with Good Manufacturing Practices (GMP) and quality management.[6]
- Submit a pharmacokinetic study of comparative bioavailability[7], proving to have the same efficacy and safety than the reference product.

4 http://registrosanitario.ispch.gob.cl/

5 To see the updated list of active ingredients compelled to demonstrate bioequivalence , click on www.ispch.cl/sites/default/files/cronograma_de_exigencia.pdf

6 See detail of GMP currently in force by clicking on: www.ispch.cl/sites/default/files/Normas_gmp.pdf

7 See ISP's guidelines for studies of comparative bioavailability by clicking on: www.ispch.cl/sites/default/files/G-Biof%2001%20-%20Gu%C3%ADa%20para%20la%20realizaci%C3%B3n%20de%20estudios%20de%20biodisponibilidad%20comparativa%20en%20formas%20farmac%C3%A9uticas%20s%C3%B3lidas%20de%20administraci%C3%B3n%20oral%20y%20acci%C3%B3n%20sist%C3%A9mica.pdf

Studies intended to demonstrate therapeutic equivalence should be submitted to the Institute of National Health (ISP)[8]. They could be conducted in Chile (by laboratories previously appointed by the ISP) or abroad. In this last case, laboratories should be authorised by health authorities of Canada, Spain, Japan, United Kingdom, Sweden or Switzerland, or by the World Health Organization (WHO), the European Medicines Agency (EMA) or laboratories certified as National Regulatory Authorities of Regional Reference – Level IV, by the Pan American Health Organization (PAHO).

Depending on the type of product, requested bioequivalence studies could be "in vivo" or "in vitro". In the first case, criteria and procedures are based on the ones requested by the FDA and the EMA.

In the second case ("in vitro" studies), companies could opt for a bio exemption procedure, which allows the conduction of comparative kinetic studies to products in the following cases:

- Products under solid, oral and fast-dissolving or release form, formulated with active ingredients meeting Biopharmaceutics Classification System (BCS) criteria and accepted by international regulations of the PAHO/WHO.
- Products formulated in new dosages, with active ingredients to be absorbed for their systemic distribution.
- Products already approved as therapeutic equivalent, but with some modifications established in the regulation.
- Products for which an "in vitro" and "in vivo" quantitative correlation has been demonstrated and having the same "in vitro" dissolution rate than the reference product.

It is important to keep in mind that ISP's bioequivalence procedures have been modified several times within the last years, in many cases to adapt them to the current practices of the FDA and the EMA, as well to the guidelines issued by the World Health Organization (WHO). Therefore, it is advisable that companies always check the regulation in force upon the Institute of Public Health (ISP), before starting a bioequivalence demonstration process.

8 Criteria used to demonstrate therapeutic equivalence are contained in the Technical Rule 131 issued by the Ministry of Health, and its further modifications. See text (in Spanish) by clicking on www.minsal.cl/portal/url/item/c36871f580b74fc7e04001016501186c.pdf

1.1.3 Biosimilar product registration

Biosimilars are biotechnological products having demonstrated they are comparable in efficacy, safety and quality versus their reference products.

For this purpose, regulation defines biotechnological products as biological products, obtained from microorganisms, blood, or living tissues, developed by genetic engineering and obtained by DNA combination techniques and monoclonal antibodies, among others.

The Institute of National Health (ISP) established a specific procedure for the registration of this type of product[9], which requirements are based on international criteria and follow WHO recommendations. Companies should submit a complete dossier, including quality comparative studies, pre-clinic and clinic studies, immunogenicity studies, etc.

1.1.4 Pharmaceutical Product Patents

Law 19.039 and its further amendments and regulations rule de patentability of pharmaceutical drugs. The amendments brought Chile's intellectual property legal framework in line with TRIPS (WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights).

In addition, Chile joined the Patent Cooperation Treaty (PCT) system in 2009, which facilitates the international filing of patents. By filing one international patent application under the PCT, applicants can simultaneously seek protection in more than 150 countries throughout the world.

To be patentable in Chile, a pharmaceutical drug must meet three requirements:

- Novelty: A drug will be new if it does not form part of the state of the art.
- Inventive step: A drug involves an inventive step if it is not obvious to a person skilled in the art.
- Industrial application: The new drug must be capable of industrial application.

Pharmaceutical product patent applications should be upon the National Institute of Industrial Property (known as "Instituto Nacional de Propiedad Intelectual" or its acronym INAPI) and follow a pre-defined procedure[10].

9 Procedure details are contained in the Technical rule 170, issued by the Ministry of Health. See the complete text (in Spanish) by clicking on www.ispch.cl/sites/default/files/Norma%20Biotecnologicos.pdf

10 For details about the pharmaceutical product patent procedure (in English), click on www.inapi.cl/en/patents

Intellectual Property laws distinguish between “primary” (on active ingredient) and “secondary” patents (on modified compounds, formulations, dosages, particular medical uses, etc.). It offers patent protection for both pharmaceutical products and processes, providing from 2005 a statutory patent life of 20 years (not extendable) from the application date. It must be noted that in Chile a pharmaceutical product patent takes in average 8 years to be granted, therefore the actual patent life would be of about 12 years.

A pharmaceutical patent must be registered in Chile to be recognized. However, if a patent has been previously requested abroad, the applicant has a one-year priority period to request it in Chile.

A patent may be revoked by means of a cancelation action filed before INAPI. The grounds for cancelling a patent according to the Chilean legislation may be any of the followings:

- It was granted to a person who is not the true inventor or assignee.
- It was granted over the basis of erroneous or evidently deficient examiner’s reports.
- It was granted in contravention of the rules of patentability (e.g. lack of inventive step or novelty). The applicable statute of limitation is five years as of the date of the patent registration.

It is important to mention that Chilean law provides for compulsory licenses for pharmaceutical products under some cases, in line with the patent protection flexibilities of the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement. In 2018 and for the first time, the Chilean Government granted a compulsory license over a valid patent for an active ingredient (Sofosbuvir), adducing “economic inaccessibility”. This precedent could open the gate for new compulsory license claims in the future, especially in the case of highly priced products.

1.1.5 Trademark protection

Even if it is not mandatory, it is recommended that companies register their trademarks if they aim to use them in Chile. They will permit to uniquely identify a company and/or product to its customers and to distinguish them from those of its competitors

It is also advisable that, before using a trademark or logo, companies should check if such signs are already registered in identical or similar terms (visually or phonetically).

In Chile, trademark protection is ruled by the Industrial Property Law (Law 19.039/ 2005)[11] and its regulations. The National Institute of Industrial Property (INAPI) is the Chilean agency for registering trademarks and copyrights.

The registration procedure can be done in person or via internet, for a fee. According to Chilean law, it is not necessary to hire a lawyer or trademark agent to file an application. Nevertheless, it is recommended in the case of companies having foreign residence, which should appoint a local representative.

Trademark protection lasts 10 years and its registration can be renewed indefinitely (for periods of 10 years at a time). The owner of a trademark could authorize a third party to use it under a license contract.

The applicable status of limitation is five years as of the date of the trademark registration. However, no status of limitation applies in case of trademarks obtained in bad faith.

A trademark must be registered in Chile to be recognized. However, if it has been previously requested abroad, the applicant has a six months priority period to request it in Chile.

In addition, famous and notorious trademarks registered abroad can claim rights in Chile over an identical or similar trademark registered, or filed for registration, for the same products, services and commercial or industrial establishments, by filing a cancellation action or by opposing a pending application.

A trademark may be revoked by means of a cancelation action filed before INAPI. The grounds for cancelling a trademark according to the Chilean legislation are any of the legal registration prohibitions. Currently, Chilean legislation does not recognize a cancelation action based on the non-use of a trademark.

1.2 Medicament Commercialization

1.2.1 Import Procedures

a) General import procedure

In the case of any import, Chilean Customs requires that each customs entry be supported by the following documents:

11 See complete text (in Spanish), by clicking on: www.leychile.cl/Navegar?idNorma=30406

- Commercial Invoice
- Certificate of Origin
- International Transport Document (Bill of Lading or Air Way Bill)
- Packing List, when necessary
- Value declaration
- Other Documents (i.e. safety certificates)

All imports of a total value exceeding USD 1,000 (FOB) require the participation of a Customs Broker. Minor imports (less than USD 1,000 FOB) can be cleared directly by importers, following a simplified procedure.

Prior import licenses are not requested by authorities. This is valid for any type of goods.

b) Duty taxes

The tax treatment applicable to imports into Chile includes the payment of customs duties, Value Added Tax (VAT) and other taxes (if applicable), all calculated on CIF value and determined under GATT valuation standards. Pharmaceutical product imports are subject only to duty taxes and VAT (19%).

The ad-valorem customs duty rate is 6%. However, goods originating in any of the countries having signed a Commercial Agreement with Chile and evidencing such condition by means of a Certificate of Origin can be benefited with a reduction or exemption of import duties.

Chile has signed 25 Commercial Agreements with 66 countries, which have granted tariff preferences which each country applies to imports.[12]

India and Chile have signed a Partial Scope Trade Agreement (PSA) giving a tariff preference (ranging from 30 to 100%) to pharmaceutical products classified under some specific HS codes.[13] This means that imports of these products pay a duty tax ranging from 0 to 4.2%.

12 Find the list of countries and the complete texts of Commercial Agreements signed by Chile, by clicking on this link: www.direcon.gob.cl/acuerdos-comerciales/

13 Find the list of pharmaceutical products benefiting of tariff preferences by clicking on www.direcon.gob.cl/wp-content/uploads/2011/03/Anexo-Chile-SA-2017.docx.pdf

c) Import procedures for pharmaceutical products

Laboratories, drug wholesalers, drugstores, public health entities and, in general any natural person or legal entity are authorized to import pharmaceutical products previously registered upon the Institute of Public Health (ISP).

Pharmaceutical ingredients can be imported only by drugstores and manufacturing laboratories. Semi-finished products can be imported only by laboratories (devoted to manufacturing, repacking and/or fractioning).

The import and commercialization of pharmaceutical products is subject to two authorizations granted by the Institute of Public Health:

- Custom Destination Certificate ("Certificado de Destinación Aduanera"), authorizing to move the products from Customs area to the establishment (meeting the requirements established by the law) where they will be stored. This authorization is requested for Customs clearance.
- Resolution for Usage and Disposition ("Resolución de Uso y Disposición), which authorizes the usage and distribution of the imported pharmaceutical products.

Both authorizations can be requested at the same time and using the same form through the ISP`s online system (GICONA). This can be done before the arrival or the goods to Chile.

Products cannot be used, commercialized or processed in any way until the Resolution for Usage and Disposition is granted.

In addition, there is a simplified procedure allowing natural persons to directly import medicines for personal usage, which could be done online[14].

1.2.2 Product labelling

Medicaments should have a primary and secondary packaging and contain a patient information leaflet.

Primary packaging should be understood as the layer of packaging used to contain the pharmaceutical product under its definitive form and which comes in direct contact with the product.

14 For details, click on www.ispch.cl/anamed/importaciones-uso-personal

On the other hand, secondary packaging is the layer of packaging that, apart from being tamper-proof, should allow containing, protecting and preserving the primary packaging.

Products can be exempted from the requirement of the secondary packaging and/or the patient information leaflet, when the primary packaging by itself can guarantee the quality of the product and is able to include the information the secondary packaging and the patient information leaflet should contain.

The labelling information should be printed on the packaging external side or stuck to it. It should not be in contact with its content. The text font should be Arial (or other rectilinear one), which size should be not smaller than 6 points.

The labelling should not contain advertising or promotion claims. In some cases, labelling can include captions or words in other languages in addition to Spanish, but they should not alter the text approved by the Institute of Public Health (ISP) during the sanitary registration process.

In case of medicaments containing only one active ingredient and with a trade mark, the generic name should be included in the labelling meeting the following requisites:

- Should be placed immediately under the name of the product or trade mark.
- Keep the same font and background colour as the name of the product
- Should be printed using a font size not smaller than a half of the font size used for the name of the product, and no smaller than 6 points.
- Should be printed in capitals.

a) Secondary packaging

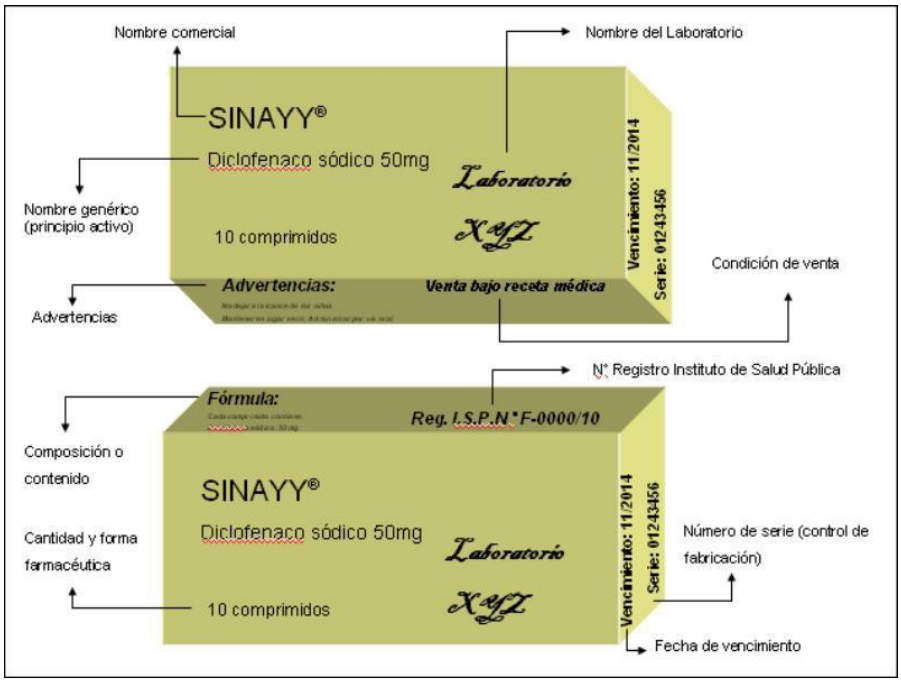
According to Supreme Decree 3/2010, Section 74, secondary packaging labelling should be in Spanish, written in easily visible characters and including at least the following information:

- Name of the product
- Dosage form (i.e. pill, tablet, capsule, syrup, etc.).
- Unitary dose in mg. or % (in case of products containing only one active ingredient).
- Non-conventional pharmaceutical release form, if it is the case (I.e. extended release caps)
- Number of units
- Name and quantity of each active ingredient and name of the excipients

Example: *"Cada comprimido recubierto contiene: Atorvastatina (como atorvastatina cálcica) 20 mg. Excipientes: Celulosa microcristalina, magnesio estearato, croscarmelosa, hipromelosa, dióxido de titanio"*.

- Name and address of the manufacturer, secondary packaging laboratory, importer or/and distributor, accordingly.
- Route of administration
- Sale condition (over the counter, only on prescription, under filed prescription or under an official prescription).
- Expiration date.
- Sanitary register number, written as "Reg. I.S.P. xxx"
- Batch identification number, written as "serie xxx" or "lote xxx"
- Storage conditions
- The caption "Mayor información en www.ispch.cl".

See example below:



b) Primary packaging

The primary packaging labelling should include at least the following information, written in Spanish and in visible characters:

- Name of the product
- Dosage form (i.e. pill, tablet, capsule, syrup, etc.).
- Unitary dose in mg. or % (in case of products containing only one active ingredient).

- Route of administration
- Expiration date.
- Sanitary register number, written as “Reg. I.S.P. xxx”
- Batch identification number, written as “serie xxx” or “lote xxx”

c) Patient Information leaflet

Prescription-only medicaments (POM) should include a leaflet at least the following information:

- Therapeutic indication authorized by the registration resolution.
- Warnings of usage, for example under certain patient conditions (I.e. pregnancy, breastfeeding, allergies, etc.) or activities (i.e. driving, using tools or machinery, etc.)
- Contraindications (i.e. patients with some diseases or medical conditions)
- Interactions (i.e. with other drugs or food/beverages).
- Side effects.
- Any other information requested by the Institute of Public Health during the product sanitary registration process.

d) Bioequivalent product labelling

Bioequivalent products should include in their secondary packages a yellow strip with the text “bioequivalente” and a “B” letter surrounded by a circle, both in red. See example:

Strip and text should be printed in at least 4 of the 6 main sides of the packaging underside, covering at least 20% of its surface.

1.2.3 Prices

Pharmaceutical product suppliers (manufacturers, importers, distributors, pharmacies and others) are compelled by law to disclose the prices of the products they sell, as well as their discount policy per volume range, temporary price offers, payment terms, guaranties, etc. Price discrimination toward small retailers or pharmacies vis-a-vis pharmacy chains is explicitly forbidden by law.

The above price information should be permanently updated and preferably published in the supplier's web site, if available.

Suppliers are obliged to separately include any additional cost in their sale invoices, such as special exhibitions, promotions, etc.

1.2.4 Brand name

The section 83 or the Chilean Health Code imposes some restrictions to pharmaceutical product fantasy names, under the following situations:

- Are identical or similar to any ICD or INN[15].
- Are identical or similar (leading to confusion) to any other product of different active ingredients or therapeutic properties.
- Are identical to other products, which sanitary register had expired less than 10 years ago (for OTC products) and less than 5 years ago, in the other cases.
- Are identical or similar to any food and cosmetic subject to sanitary control.
- Induce to wrong use or promotes auto medication.

1.2.5 Advertising and Promotion

In Chile, only OTC medicines are authorised to conduct advertising and promotion activities to final consumers. These activities should be previously authorised by the Institute of National Health (ISP) and should be in line with what is stated in the product's sanitary register.

Advertising should only communicate the information contained in the patient leaflet, totally or partially.

15 ICD (International Common Denomination) and INN (International Non-proprietary Name) are nomenclatures which facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each ICD or INN is a unique name that is globally recognized and is public property.

The donation of medicines for advertising purposes is forbidden, with the exception of samples to physicians. At this respect, any product information for health professionals should be given exclusively to those authorised to prescribe medicines and to pharmacy chemists.

In addition, incentives (understood as payment, gifts, services or economic benefit)[16] intended to induce the usage, prescription, sale or administration of pharmaceutical products to any person are forbidden.

1.3 Government's Health Protection Programs

Chilean Government has in place some initiatives and programmes intended to mitigate health expenses of Chilean population, and specifically those related to medicine purchase.

The impact of these programs has been the possibility to access to medicines – in many cases of unattainable costs – for persons suffering from catastrophic or chronic diseases, many of whom were unable to finance them.

1.3.1 Ricarte Soto Law

Law No. 20.850 enacted on 2015 (best known as "Ley Ricarte Soto") created a financial protection system for high-cost diseases, ensuring their diagnoses and treatments based on medicines, medical devices and high-cost foods with proven effectiveness. for both public and private health insurance beneficiaries.

Although the law initially covered only 11 pathologies, it has been extended to others since then. Moreover, on July 1, 2019, nine high-risk and high-cost diseases were also added. This means that 27 diseases are now covered under the law, including Amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), multiple sclerosis, primary immunodeficiency disease, lupus, ulcerative colitis, and HER2-positive breast cancer. It is expected other pathologies will be added in the future.

1.3.2 Universal Access with Explicit Guarantees (AUGE-GES)

16 This rule has been added in 2015 mainly to prohibit a common practice (known as "canela") of pharmaceutical laboratories of giving monetary incentives to pharmacy clerks, subject to the achievement of predefined sales goals of certain products.

In 2004 and through Law 19.996[17], Chilean government implemented significant health reform known as Universal Access with Explicit Guarantees ("Acceso Universal con Garantias Explicitas" - AUGE or GES)[18], which mandated health insurers to adopt a wide benefits package defined via explicit legal guarantees for all beneficiaries.

For a list of 85 pathologies, Chileans are granted the right to access to health care (including drugs) within a certain period of time and with maximum co-payment of 20% of the actual cost.

Illnesses representing the highest number of patients under the AUGE-GES system are arterial hypertension, depression, diabetes, and hypothyroidism. It is expected that new pathologies will be added to the list in years to come, as it has from AUGE -GES beginning.

1.3.3 FOFAR Program

In 2014 and through Exempt Resolution No. 535, Chilean government created a program called FOFAR ("Fondo de Farmacia"), that provides some specific drugs – free of cost – to persons belonging to public health care system and suffering from some chronic, non-communicable diseases: arterial hypertension, diabetes mellitus II and high cholesterol.

1.4 Recent regulations

1.4.1 CENABAST intermediation and price regulation

Searching for ways to beat back rising drug costs, the Parliament has recently approved a new law (law 21.198) concerning the role of the National Health Service System (CENABAST)[19] and modifying the Health Code, which has been enacted on January 8, 2020

This law allows CENABAST:

17 To see the complete text of Law 19.996 (in Spanish) , click on this link: www.leychile.cl/Navegar?idNorma=229834

18 For further details on AUGE-GES system, click on this link: www.supersalud.gob.cl/difusion/665/w3-propertyvalue-1962.html

19 The National Health Service System Cenabast (www.cenabast.cl) is a public agency belonging to the Ministry of Health, in charge of the procurement and distribution of medicaments, medical supplies and goods. Before this law, Cenabast clients belonged only to the public sector, that is public hospitals and primary healthcare centres, as well as the Ministry of Health for their complementary feeding and health programs.

- To act as an intermediary in purchasing medicines and medical devices, between manufacturers/distributors and private customers, such as pharmacies and non-profit health institutions and hospitals.
- To be able to set price caps to final buyers to its private costumers, applicable to the products CENABAST sells to these latest. This agency should establish a consultative council to recommend the maximum price of a drug.
- To import pharmaceutical products without the need of a previously-approved procurement contract, in case of justified reasons, such as product shortage or insufficient offer in the internal market, as well as in case of international commercial practice or regulation.
- To directly ask for pharmaceutical product registration and distribution authorization to the Institute of Public Health.

The law considers certain deadlines (from law enacting date) for CENABAST to manage intermediation requests:

- 90 days, for requests from pharmacies being the only medicine outlet in the towns they are located, and from pharmacies considered as small companies, according to law (Law 20.416, article 2).
- 12 months, for requests from small pharmacies belonging to regional chains, not included in Law 20.416, article 2.
- 24 months, for requests from non-profit health institutions and hospitals and from national chains.

It is important to take in mind that CENABAST will only serve as intermediate between local laboratories and pharmacies, but logistics and payment should be done directly between these latest. This means that CENABAST will not buy, storage of distribute products to further sell them to private pharmacies, except in the case of the products it decides to import directly. CENABAST – trough calls for bids and supply agreements – will agree the prices of products with suppliers and allow pharmacies to benefit of the lower prices it gets.

This initiative seeks to reduce final medicine prices to consumers. Historically, CENABAST has bought pharmaceutical products from laboratories at prices 75% lower than pharmacies prices to consumers. It is expected that CENABAST's advantage of buying cheaper would be passed to final consumers.

Nevertheless, the real impact of this law will depend on the interest of pharmacies of buying through CENABAST and benefit of its intermediation. This will, in turn, depend largely on the price caps this agency will set, that is, if these latest would let them enough

margin to cover their expenses and have profits. It will also depend on the number and type of pharmaceutical products CENABAST will have available for intermediation. It is expected that CENABAST will manage 500 different products (100 in the first stage) from an estimated total of 8.000 sold in Chile. These 500 products are supposed to represent 80% of total pharmaceutical sales in the country. However, these products could not necessarily correspond to the buying preferences of each individual pharmacy.

This new law will also mean a significant change in the CENABAST's role, considering that until law enactment it was only in charge of ensuring the supply of drugs, food, supplies and equipment to the Chilean public health network. Some experts believe that it will require major internal changes and budget adjustments, which will not be easily implemented in the short and medium term, making uncertain the fulfilment of deadlines envisaged by the law.

The impact of the authority given to CENABAST to import directly without the need of a supply contract and in case of justified circumstances (i.e. product shortage, insufficient offer, international commercial practice or regulation, etc.) is still uncertain. Even if these circumstances are wide and unprecise and therefore could be applicable in several cases, in practice it could be difficult to CENABAST to prove and duly justify them, as mandated by the law.

1.4.2 E-commerce

In January 2020, the Ministry of Health issued a Supreme Decree ruling the e-commerce of pharmaceutical products. This regulation is currently at the Comptroller General of the Republic for recording process.

This Decree imposes obligations to online pharmacies, such as requirements for medicament delivery through third parties, prohibition to advertise or promote pharmaceutical products in sales websites and strict measures to protect buyers' personal data.

Importantly, this Decree allows the existence of pharmacies dedicated exclusively to online sales, opening the gate to new competitors in the field of medicine distribution. Thus far, digital platforms for medicament online sales should necessarily be associated to already existing pharmacies.

1.4.3 Bioequivalence Homologation

A recent Supreme Decree of the Ministry of Health allows bioequivalent products already approved by international health authorities to get, with minimum formalities, their validation as bioequivalent in Chile. This regulation is currently on Comptroller General of the Republic recording process.

As of today, the Food and Drug Administration (FDA), as well as Brazilian and Colombian health agencies are accredited for this purpose. It is expected that, in the next future, new foreign agencies will be added to the list.

This initiative will drastically decrease costs for laboratories, as well as to shorten deadlines of bioequivalence demonstration procedures, allowing a faster entry into the Chilean market.

1.4.4 Pharmacies` minimum stock

In October 2019, the Ministry of Health, through Exempt Resolution 1831, increased to 239 the number of medicines that pharmacies should keep permanently in stock in their premises (known as “Petitorio Mínimo”). Active ingredients compelled to demonstrate their bioequivalence were included in the list, as a way to ensure medicament interchangeability.

2. Future legislation and regulation

2.1 Drug Law II (“Ley de Fármacos II)

The Chilean Congress is currently discussing the so-called Bill “Drugs II” (2015), which seeks to amend the Health Code and Intellectual Property Law, as well as to update some regulations.

The previous and most significant reform of the Health Code and other health-related normative bodies was the law known as “Drug Law I” (Ley de Fármacos I). It was enacted on 2014 and modified several provisions regarding the commercialization of pharmaceutical products, including:

- Prescription of pharmaceutical products. When prescribing a specific brand name medicine, physicians are compelled to include its generic name.
- Exhibition, expenditure and sale of direct sale products (OTC), which are now allowed to be exhibited in pharmacies, in auto service shelves.
- Fractioning of medicine packages, in order to allow consumers to buy the exact number of pills they need for their medical treatment.
- Pharmacies shifts.
- Price information in pharmacies (see section 1.2.3).
- Advertisement and promotion of pharmaceutical products (see section 1.2.4).
- Application of voluntary licenses.

In relation to the bill "Drugs II", as of today it was approved at the Chamber of Deputies and passed to the Senate in December 2019.

In general terms, the law draft passed to the Senate contains the following main topics:

- Physicians will be compelled to prescribe medicaments under the "International Common Denomination (ICD) or International Non-proprietary Name (INN)" of the compound.[20]
- OTC pharmaceutical products could be sold in other retail stores different than pharmacies, such as supermarkets and convenience stores.
- Pharmacies would be obliged to inform customers on the generic versions available for the drugs prescribed by doctors (under the ICD/INN nomenclature).
- Medicine packaging will include the ICD or INN in a greater size than its trademark or brand name. [21]

- To strengthen even more the therapeutic exchangeability, already initiated in Law Drug I.
- To create a medicine price monitoring system[22]

The original draft bill included previsions to avoid the vertical integration of laboratories (manufacturers and distributors) and pharmacies. Nevertheless, this subject was

20 If approved, it would mean that physicians will not be able to prescribe a medicine by its brand name. This provision seeks to avoid the current and generalized practice of laboratories indirect of giving incentives (i.e. travels, invitations to congresses, etc.) to physicians to motivate the prescription of their brands. Nevertheless, some experts believe that this measure will hand over power of privileging specific brands from doctors to pharmacies, which would be in charge of recommending brands that meet the prescribed ICD compound.

21 The ICD size should be at least one third of the main faces of the packaging, while the trademark may not exceed one fifth of the space used by the ICD.

22 The purpose of this provision is to create the basis for a future draft law intended to set price bands for medicines, which is an aspiration already announced by authorities.

eliminated during discussions in the Chamber of Deputies. It is still unclear if they will be re-included by the Senate.

In January 2020, the Senate Health Commission recommended to reject 32 of the 80 modifications introduced by the Chamber of Deputies. Therefore, and according to legislature procedures, a Joint Committee was created – composed by equal number of deputies and senators – to intend to reach an agreement.

Given this, it is expected that Bill Drug II discussions in the Parliament will continue for several more months, extending even more the already 4-year period this draft law has been debated.

2.2 Other potential future laws and resolutions

In October 2019, the Government launched a new Medicament National Policy including 31 initiatives[23] intended to reduce Chilean families` spending on medicines and to better ensure the quality of pharmaceutical products sold in Chile.

The implementation of some of these initiatives would require new laws or regulations. Therefore, they are a good overview of potential future changes in Pharmaceutical market legislation framework.

Some of these initiatives are:

- Fractioning of medicines packages implementation. Fractioning was already addressed in Drug Law I, but it is still not mandatory for the pharmaceutical industry, due that its regulation (ruling its practical implementation) has not been issued. It is currently being prepared by the Ministry of Health.
- Good Manufacturing Practices (GMP) compliance, making it compulsory for all already sanitary registered products and for the ones to be registered in the future.
- Simplification of sanitary registration procedures, reducing deadlines to a maximum of 3 months.
- Price information, which would consist in a regulation intended to require pharmacies (physical and online) to automatically inform their prices to authorities.

23 See details by clicking on: www.minsal.cl/politica-nacional-de-medicamentos/30-medidas/