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1 Regulatory Framework

1.1 Please list and describe the principal legislative and regulatory bodies that apply to and/or regulate pharmaceuticals, medical devices, supplements, over-the-counter products, and cosmetics.

The following legislation regulates pharmaceuticals, medical devices, cosmetics and supplement products:

- General Law of Health (Law N° 26842);
- Law on Pharmaceutical Products, Medical Devices and Sanitary Products (Law N° 29459);
- Regulations for the Registration, Control and Sanitary Surveillance of Pharmaceutical Products, Medical Devices and Sanitary Products (Supreme Decree N° 016-2011-SA) and amendments;
- Regulations on Pharmaceutical Establishments (Supreme Decree N° 014-2011-SA) and amendments; and
- Decisions 516 and 833 of the Andean Community (Harmonisation of legislation on cosmetic products in the Andean Community).

Law N° 29459 is the main legislation that regulates pharmaceutical products, medical devices, sanitary products, pharmaceutical establishments (laboratories, storehouses, drugstores and pharmacies) and activities related to the marketing, promotion, advertising and prescription of the aforementioned products.

The General Directorate of Medicines, Supplies and Drugs (Digemid) – a public entity that is part of the Ministry of Health – is the competent national authority in charge of granting all types of marketing authorisation and authorisations for companies dedicated to the manufacturing, importation, distribution and commercialisation of such products.

1.2 How do regulations/legislation impact liability for injuries suffered as a result of product use, or other liability arising out of the marketing and sale of the product? Does approval of a product by the regulators provide any protection from liability?

According to Law N° 29459, the manufacturer and titleholder of products produced locally is responsible for the quality of the products. In case of imported products, the responsibility is assumed by the titleholder of the marketing authorisation. Said Law does not include a chapter on how said responsibility should be assumed or demanded by an end user of the product (consumer). The obtainment of the marketing authorisation is not an exemption from liability. This is a requirement that must be fulfilled in order to import, distribute, store or commercialise drugs and medical devices; therefore, the approval is an obligation and does not grant any kind of protection.

Companies that cause damages to consumers through defective products are subject to strict liability, and must pay compensation in accordance with the provisions of the Civil Code in the corresponding judicial process. However, in practice it is very rare to have lawsuits seeking compensation, as judicial cases can take many years and the amounts are not significant.

Furthermore, product liability is ruled by the Consumer Protection Code (Law N° 29571), which provides that consumers are entitled to the repair or replacement of the product, performance of a new service, or a refund of the consideration paid in certain cases, such as when: (a) materials, elements, substances or ingredients contained in products do not conform to the specifications offered; (b) the product, because of its deficiencies in manufacturing, processing, structure, quality or health or latent defects, is not suitable for the use for which it is intended; or (c) delivery of the product or performance of the service is not made in a timely manner and is not useful for the consumer.

1.3 What other general impact does the regulation of life sciences products have on litigation involving such products?

Generally speaking, regulation of life sciences products has a stronger impact in administrative instances than in judicial instances. In administrative cases, companies are sanctioned with fines and/or temporary or definitive closure of the establishment, as well as being obliged to comply with corrective measures (only if the infringing conduct has no effects or impact on the market can the sanction be a warning); however, they do not seek consumer indemnity. Aside from the fines imposed, there are other measures that the administrative authorities can order, such as the following:

(i) Precautionary measures: these measures can be ordered at any stage of the proceeding. These are, e.g., the cessation of the infringing action, closure of an establishment, banning of a website, immobilisation of goods, etc.

(ii) Corrective repair measures: these measures are aimed at compensating any *direct* monetary consequences resulting from the infringement (e.g., giving back the money paid by the consumer, changing the product, etc.).

(iii) Corrective supplementary measures: these measures are aimed at reverting the effects of infringing conduct or preventing them from happening again in the future (e.g., publication of a rectification).

(iv) Fines for non-compliance: if a fine is not paid or a measure is not complied with, additional sanctions can be ordered.

Indemnity is only established in judicial cases. The procedure can last many years and the plaintiff must prove the harm caused in order to try to obtain compensation for damages, which, in most cases, do not involve large amounts of money.

1.4 Are there any self-regulatory bodies that govern drugs, medical devices, supplements, OTC products, or cosmetics in the jurisdiction? How do their codes of conduct or other guidelines affect litigation and liability?

There are some private associations, such as the National Association of Pharmaceutical Manufactures (ALAFARPE), the Lima Chamber of Commerce, the Latin American Association of Pharmaceutical Laboratories, among others, that have their own codes of ethics or conduct which they expect their members to follow. Because the cases that are brought to said private associations are not public, they are treated as confidential information, and it is not possible to know their impact.

Since enrolment in these self-regulatory codes is voluntary, lack of compliance with the rules included in these codes would not have a major impact on a judicial case.

1.5 Are life sciences companies required to provide warnings of the risks of their products directly to the consumer, or to the prescribing physician (i.e., learned intermediary), and how do such requirements affect litigation concerning the product?

Indeed. Warnings of the risks of the products must be included not only on the label of the drugs, medical devices and cosmetic products, but also on each insert (if applicable). It is mandatory to do this. Warnings are considered relevant information and therefore not providing one will not only be considered an infringement of Law N° 29759, but also of the Consumer Protection Code (Law N° 29571) for not providing proper information so that the consumer could make an adequate and informed decision.

Failure to provide warning about the products will not only immediately trigger the titleholder's responsibility of the marketing authorisation, but also the responsibility of the companies that participate in the distribution and commercialisation channel.

2 Manufacturing

2.1 What are the local licensing requirements for life sciences manufacturers?

Laboratories – life sciences manufacturers – require a Health Authorisation to operate.

Laboratories shall comply with the requirements established in the Good Manufacturing Practices, Good Laboratory Practices, Good Storage Practices and Good Pharmacovigilance Practices.

2.2 What agreements do local regulators have with foreign regulators (e.g., with the U.S. Food and Drug Administration or the European Medicines Agency) that relate to the inspection and approval of manufacturing facilities?

Certificates of Good Manufacturing Practices issued by Competent Authorities with high sanitary surveillance are acceptable by Digemid. The countries with high sanitary surveillance are: Australia; Austria; Belgium; Canada; Denmark; France; Germany; Hungary; Ireland; Italy; Japan; Korea; the Netherlands; Norway; Portugal; Spain; Sweden; Switzerland; the United Kingdom; and the United States of America.

Additionally, Article 113° of Supreme Decree N° 014-2011-SA states that a Certificate of Good Manufacturing Practices, granted by the competent authorities from other countries with whom mutual recognition agreements have been signed, is also considered valid. However, to date, no mutual recognition agreements have been executed.

2.3 What is the impact of manufacturing requirements or violations thereof on liability and litigation?

If non-compliance with the manufacturing requirements is detected, there is a system of penalties which may be imposed. These could range from financial penalties to the closure of an establishment. In order to protect the health of the population, the security measures adopted by the Peruvian health authority are based on the following principles:

(i) Protection of people's health and life.
(ii) Measures should be applied objectively, impartially and independently.
(iii) Measures should be proportional to the aim pursued.

Immediate security measures can be applied, such as: withdrawal of products from the market; destruction of products, supplies, materials, equipment or machinery; and discontinuation of the manufacturing process at any of its stages, etc. (Article 49° of Law N° 29459).

Further, it is important to mention that the pharmacist who assumes the technical direction of a laboratory is responsible for meeting the quality requirements of the products that are made, imported, exported, stored, distributed or dispensed therein, as appropriate. Likewise, he/she is responsible for compliance with Good Practices.

At the same time, the responsibility of the technical director is shared jointly with the owner or legal representative of the laboratory.

3 Transactions

3.1 Please identify and describe any approvals required from local regulators for life sciences mergers/acquisitions.

The Peruvian Merger Control Law was published on January 7, 2021 (the "Merger Control Law") and entered in full force and effect on June 14, 2021.

Operations under the Merger Control Law include any act or transaction involving a transfer or change of control, directly or indirectly, in a company or part of a company, for example: (a) mergers; (b) share purchases; (c) the creation of a joint venture or any other similar arrangement involving the acquisition of joint control over one or more economic agents; and (d) asset purchases.

The transactions subject to prior authorisation are those that meet the following: (a) they imply a transfer or change of control[1] in a company or part of a company; (b) they are executed in Peru or abroad but have effects in all or part of Peruvian territory; and (c) they reach or meet, jointly, the following thresholds:

(i) the aggregate value of annual sales or gross income **or** the book value of the assets in Peru (and their respective economic group)[2] involved in the transaction during the past tax year has reached an amount equal or greater than 118,000 Tax Units (approximately US$169MM);[3] and

(ii) the aggregate value of annual sales or gross income **or** the book value of the assets in Peru, reported by at least two of the companies involved in the transaction (individually evaluated) during the past tax year, has reached an amount equal to or greater than 18,000 Tax Units, each (approximately US$25 MM for each company and its economic group). The Merger Control Law only considers local turnover for the thresholds' calculation.

In the event of a merger or acquisition of joint control, all economic agents involved in the transaction must submit a joint request for authorisation before the Peruvian Antitrust Authority (INDECOPI). In all other cases, the request for authorisation must be submitted by the economic agent that is acquiring control over all or part of one or more economic agents.

Finally, please consider that even when a concentration does not meet the above-mentioned thresholds, INDECOPI may act *ex officio* when there are reasonable indications to consider that the transaction may generate a dominant position or affect effective competition in the relevant market. This action may only be triggered up to one year after the transaction's closing date.

Non-compliance with the provisions set forth in the prior control regime may lead to the imposition of a fine of up to 12% of the infringing company's or its economic group's sales or gross income during the calendar year immediately prior to the issuance of INDECOPI's resolution. Additionally, INDECOPI may establish corrective measures aimed at reversing the unlawful concentration.

3.2 What, if any, restrictions does the jurisdiction place on foreign ownership of life sciences companies or manufacturing facilities? How do such restrictions affect liability for injuries caused by use of a life sciences product?

There are no restrictions on ownership of life sciences companies. The only restriction for a foreign natural person or legal entity is that, within a distance of 50 kilometres from the border, foreigners may not acquire or possess under any title, directly or indirectly, land, mines, forests, water, fuel or energy sources, whether individually or in partnership, under penalty of losing to the State that right so acquired. The sole exception involves cases of public need expressly determined by executive decree and approved by the Ministry Council.

Under Peruvian law, product liability is ruled under the Consumer Protection Code and the Civil Code. The Consumer Protection Code applies to any consumption relationship (established between consumer and supplier) entered into in Peruvian territory or whose effects are performed therein. If the Consumer Protection Code is thus not applicable, then product liability shall be regulated by the general rules provided in the Civil Code; however, those Peruvian laws are applicable.

The Consumer Protection Code provides that consumers are entitled to repair or replacement of the product, performance of a new service, or a refund of the consideration paid in certain cases, such as when: (a) materials, elements, substances or ingredients contained in products do not conform to the specifications provided; (b) the product, because of its deficiencies in manufacturing, processing, structure, quality, health or latent defects, is not suitable for the use for which it is intended; or (c) delivery of the product or performance of the service is not made in a timely manner and is not useful for the consumer.

Suppliers that cause damages to consumers through defective products are subject to strict liability and must pay compensation in accordance with the provisions of the Civil Code in the corresponding judicial process. When there are several suppliers of a product (for instance, manufacturer and distributor), they all shall be jointly liable. Notwithstanding the foregoing, each supplier has a right of recourse against the supplier that provided the defective product or caused the defect. A supplier is also administratively liable for any breach of the Consumer Protection Code. The proceeding shall be conducted before INDECOPI, which may impose fines of up to US$640,000 (approximately). INDECOPI may also impose remedial and complementary corrective measures.

The Civil Code does not contain specific product liability rules. Nonetheless, general principles of civil liability contained in the Civil Code empower the victim of damage caused by a defective product to claim the corresponding compensation.

The Civil Code regulates the liability arising from a contractual breach. When the seller and the buyer are bound by a contractual relationship and the damage suffered by the buyer is a direct consequence of the breach by the seller in the performance of its obligations, civil liability for those damages shall be ruled under contractual liability. In this case, the seller shall be liable as long as any degree of fault is demonstrated. For instance, if the manufacturer (or distributor) demonstrates that it implemented a quality-check system, it may not be liable for the damages caused to the buyer.

The Civil Code also provides rules regarding compensation for latent defects existing in the moment of transfer of title. Latent defects are those that the purchaser cannot detect when acting diligently. Under Article 1508 of the Civil Code, the purchaser of a fungible defective product is entitled to require, in place of sanitation, the delivery of another of the same kind. Alternatively, under Article 1511, the purchaser is entitled to require the termination of the contract, the return of the defective product to the seller and the reimbursement of the paid price. Otherwise, under Article 1513, the purchaser may require a reduction in the paid price, retaining ownership of the product. Remedies provided by Articles 1511 and 1513 expire after three months. However, note that the buyer may contractually waive these specific compensation rights. The waiver shall be ineffective in case of gross negligence or wilful misconduct of the seller.

Finally, when there is no contractual relationship between seller and buyer (for instance, between the manufacturer and the final user), the seller may also be liable under tort liability. Article 1970 of the Civil Code provides that if someone causes damage to another by means of a risky or dangerous good or the exercise of a risky or dangerous activity, it must compensate the victim of the damage. This Article incorporates the strict liability principle in the Peruvian tort system, under which no degree of fault must be demonstrated. Peruvian scholarship argues that a defective product is a risky product and, therefore, when there is no contractual relationship between the seller and the buyer and the defective product causes damages to the buyer, the seller is subject to strict liability.

Compensable damages on extra-contractual liability include loss of profit, damages to the person and moral damages, provided there is a relation of adequate causality between

the fact causing the damage and the damage produced. An adequate cause is one that in ordinary circumstances determines, produces or has the effect of producing the damage.

Furthermore, damages must be proven in order to be recoverable, although the Courts may use their criteria and discretion when evaluating the damages. The party who alleges damages must prove its existence and quantum. If the magnitude and amount of damage cannot be determined, compensation will be fixed according to the Court's criteria, considering the material difficulty in proving the value or amount of certain damages, because of its nature or the circumstances involving such damages.

If criminal liability is determined to exist by the Peruvian Courts due to illegal acts carried out by legal representatives of the company in the execution of their duties, such liability will only be applicable to the company's representatives involved in such illegal acts. Due to the nature of our criminal legal system, criminal responsibility is only applicable to individuals and not legal entities. The indemnification will be calculated based on the damages, loss of profit and moral damages caused to the Peruvian State.

4 Advertising, Promotion and Sales

4.1 Please identify and describe the principal legislation and regulations, and any regulatory bodies, that govern the advertising, promotion and sale of drugs and medical devices, and other life sciences products.

The following legislation governs advertising of pharmaceutical products and medical devices:

- General Law of Health (Law N° 26842);
- Law on Pharmaceutical Products, Medical Devices and Sanitary Products (Law N° 29459);
- Regulations for the Registration, Control and Sanitary Surveillance of Pharmaceutical Products, Medical Devices and Sanitary Products (Supreme Decree N° 016-2011-SA) and amendments;
- Regulations on Pharmaceutical Establishments (Supreme Decree N° 014-2011-SA) and amendments;
- Administrative Directive that regulates the activities of medical sales representatives or other actors of pharmaceutical companies in Health Facilities (Ministerial Resolution N° 413-2015/MINSA);
- Ministerial Resolution N° 474-2020-MINSA that approved the Technical Health Standard on Ethical Criteria for the Promotion and Advertising of Pharmaceutical Products, Medical Devices and Health Products;
- Law on Suppression of Unfair Competition (Legislative Decree N° 1044); and
- Consumer Protection Code (Law N° 29571).

The regulatory bodies are:

- the Unfair Competition Commission of INDECOPI;
- the Consumer Protection Commission of INDECOPI; and
- Digemid.

It is important to mention that advertisements do not require the prior authorisation of any authority. Supervision and control take place after the advertisement is released (*ex-post* control). The principal rule is that the promotion and advertising of drugs and medical devices for sale with a medical prescription must be addressed exclusively to physicians. Therefore, it is prohibited to promote and advertise drugs under medical prescription for the general public. This prohibition is also applicable to health establishments (hospitals, clinics, etc.), since Article 195 of Supreme Decree N° 016-2011-SA states that the installation of modules or spaces in such places, to carry out promotion and advertising activities or delivery of drugs or other pharmaceutical products, will not be authorised.

In addition, as a general rule, Law N° 26842 states that advertisements must not contain exaggerations or other inaccurate information on their properties, which may lead consumers to error, and must not encourage self-medication and irresponsible use.

4.2 What restrictions are there on the promotion of drugs and medical devices for indications or uses that have not been approved by the governing regulatory authority ("off-label promotion")?

Such promotion is not possible.

The information provided in a promotion or in advertising must coincide with the information authorised, along with the marketing authorisation. Likewise, according to Supreme Decree N° 016-2011-SA, the promotion and advertisement of drugs must include information that appears in the technical specifications and must be legible, clear, truthful, accurate, complete and updated, and in the Spanish language.

4.3 What is the impact of the regulation of the advertising, promotion and sale of drugs and medical devices on litigation concerning life sciences products?

Most of the litigation related to advertising and promotion of drugs and medical devices is resolved by the Unfair Competition Commission of INDECOPI, which is the national administrative entity responsible for the verification of compliance with the rules governing advertising regarding all kinds of products (including drugs, medical devices and cosmetics). Such entity is empowered to order the cessation of advertising, as well as to impose fines. In fact, the fines imposed on pharmaceutical companies are usually bigger than in other cases, because they involve providing or not providing proper information that could affect the end user's health.

Many of the cases regarding advertising of drugs are considered unfair competition conduct in the manner of acts of deception (which consist of providing information or statements that mislead regarding the nature, method of manufacture or distribution, characteristics, capacity for use, quality, quantity, price, conditions of sale or acquisition and, in general, regarding the attributes, benefits or conditions corresponding to the goods; as well as the dissemination of testimonial advertising not supported by authentic and recent experiences of a witness) or acts against the legality principle (which consist of advertising that does not respect mandatory regulations of Law N° 29459 and the Rules).

The determination of the existence of an act of unfair competition does not require proof of the awareness or of the actual committing of such act. It is not necessary to prove that such act causes actual harm to the detriment of another competitor, consumers or economic public order; the mere possibility of causing harm is enough.

5 Data Privacy

5.1 How do life sciences companies that distribute their products globally comply with data privacy standards such as GDPR and other similar standards?

The Peruvian Personal Data Protection Law enacted by Law N° 29733, and its regulations approved by Supreme Decree N° 003-2013-JUS, apply to personal data contained or destined to be contained in a public or private personal database to be processed in Peru.

The EU's Data Protection Directive (Directive 95/46/EC) has inspired Peru's Personal Data Protection Law. However, since the General Data Protection Regulation (GDPR) came into force on May 25, 2018, multinational companies have sought to harmonise their local data protection policies in the light of the new EU legal framework. For example, some are reviewing their Binding Corporate Rules (BCRs), and Codes of Conduct, etc., to assess whether or not there are requirements that may conflict with local laws, in order to allow them to reach GDPR compliance whilst avoiding contingencies in the light of Law N° 29733.

It is worth noting, however, that the new regulations of the Peruvian Personal Data Protection Law were approved by Supreme Decree N° 016-2024-JUS and will enter into force on March 30, 2025. These new regulations are inspired by the GDPR.

5.2 What rules govern the confidentiality of documents produced in litigation? What, if any, restrictions are there on a company's ability to maintain the confidentiality of documents and information produced in litigation?

Law N° 29733 does not expressly regulate the processing of personal data in the context of litigation. However, note that personal data potentially contained in documents, evidence or the like is still protected under the local data protection framework. This protection extends to any personal data that may be contained within these documents.

However, much of the processing of data will be carried out relying on a legitimate interest (e.g., asserting or defending a legal right at the Courts). That being said, we recommend that data processing be kept to a minimum and only concern truly relevant data. Irrelevant data could be anonymised or redacted. Finally, confidentiality and security during processing should be maintained at all times.

Unlike arbitration, judicial litigation is not confidential. Documents and general information produced in judicial litigation (resolutions or any judicial decisions) can be known by anyone.

Regarding documents treated as evidence in judicial litigation, although only the parties and the judge can access them easily, there are no legal restrictions to maintain their confidentiality. Only those documents that have been previously subject to a confidentiality agreement, or that are legally considered trade secrets, would be declared confidential.

5.3 What are the key regulatory considerations and developments in Digital Health and their impact, if any, on litigation?

The health sector is subject to extensive laws and regulations, including but not limited to the protection of personal data. The health sector in Peru is still not heavily technology-based in comparison to developed countries. However, when making use of technological tools that process personal-health-related data, it is important to bear in mind that it is considered sensitive information and, as such, there is a series of requirements that must be fulfilled. Among others, these requirements include:

- obtaining the prior, informed, express and unequivocal written consent of the individual whose data is being processed;
- registering their databases containing personal data and reporting cross-border transfers of such data to the Peruvian National Authority for Personal Data Protection;
- adopting technical, organisational and legal measures to guarantee the security of the personal data they hold, which must be appropriate to the nature and purpose of the personal data involved; and
- maintaining the confidentiality of the personal data.

Notwithstanding the foregoing, the consent of the individual whose data is collected is not required when, in the light of risky circumstances, the data is processed within the healthcare network for the rendering of healthcare services to such individual, including prevention, diagnosis or appropriate treatment. In addition, such consent is not required when processing is needed for: compelling reasons in the public interest contemplated by law; treatment for public health reasons; or epidemiological or similar studies. In addition, under the General Health Law (Law N° 26842), data related to the provision of healthcare services, including printed or electronic health records, is protected, and healthcare facilities and professionals may face administrative, civil or criminal liability for disclosing such information to third parties, subject to certain exceptions.

6 Clinical Trials and Compassionate Use Programmes

6.1 Please identify and describe the regulatory standards, guidelines, or rules that govern how clinical testing is conducted in the jurisdiction, and their impact on litigation involving injuries associated with the use of the product.

Law N° 26842 provides that health protection is a matter of public interest and, therefore, the State is responsible for regulating, overseeing and promoting health protection, and the State promotes scientific and technological research in the health field. Article 28 of the mentioned Law provides that experimental research involving human beings must comply with special legislation on this matter and with the ethical principles contained in the Declaration of Helsinki, as well as in successive declarations updating said principles.

The Clinical Trials Regulations approved by Supreme Decree N° 021-2017-SA, and the Manual of Procedures approved by Resolution N° 279-2017-J-OPE/INS, are the regulations that govern clinical trials in Peru. These Regulations are aimed at establishing the procedure to be followed to authorise and perform clinical trials in Peru and take subsequent action in relation thereto.

Supreme Decree N° 021-2017-SA expressly indicates that the sponsor and the principal investigator are legally liable for providing free medical attention to the subject under investigation due to any harm suffered during a clinical trial. The sponsor is also obliged to grant compensation for the damages caused to the subject without prejudice to its obligation to obtain insurance prior to the beginning of the clinical trial.

As per judicial cases involving injuries associated with the use of the product, there are no special rules other than those that govern evidence in a civil action, according to the Code of Civil Procedure. Those rules are related to: (i) offering any type of proof to the judge, according to the principle of burden of proof; (ii) the kind of evidence that could be submitted, such as documents, witness statements, an expert report and judicial inspections; and (iii) the schedule of evidentiary hearings.

In addition, offering the judge evidence that demonstrates liability, leading him/her to be convinced of a certain position, is the most important aspect, and will determine a positive judicial decision.

6.2 Does the jurisdiction recognise liability for failure to test in certain patient populations (e.g., can a company be found negligent for failure to test in a particular patient population)?

No. Liability for failure to test in certain patient populations is not recognised.

Exhibit 1 of Supreme Decree N° 021-2017-SA states that the research protocol guide must inform the target population to which the investigational product will be applied and justify this selection.

6.3 Does the jurisdiction permit the compassionate use of unapproved drugs or medical devices, and what requirements or regulations govern compassionate use programmes?

Yes. Compassionate use of unapproved drugs is permitted. In Peruvian regulations, it is referred to as post-study access.

Article 115° of Supreme Decree N° 021-2017-SA sets out that post-study access is understood to mean free availability to the trial subject to the investigational product used in a clinical trial – even if it has already obtained sanitary registration in the country – after the study has been completed or if his/her participation in the study has ended. Before the beginning of the study, post-study access must be contemplated, and this information must be provided during the informed consent process.

In this regard, the following matters will be taken into account: the severity of the medical condition of the subject; the expected effect of withdrawing or modifying the medical treatment (if the suspension of the treatment can adversely affect his/her health or wellbeing); the lack of satisfactory therapeutic alternatives in the country for the medical condition of the trial subject; and the availability of enough information about the efficacy, safety and risk-benefit balance of the intervention.

To use an investigational product under post-study access conditions, it should have been proven to be beneficial for the trial subject, in the opinion of the principal investigator, in which case it will continue to be used to the extent it is beneficial.

Post-study access authorisation can be granted through the following mechanisms:

- Authorisation of a clinical trial carried out as part of an extension study, which will be granted by the Office of Research and Technological Transfer (OGITT in Spanish) of the National Institute of Health (INS in Spanish).
- Authorisation by Digemid of an investigational product that has been proven to be beneficial for the trial subject, at the sole discretion of the principal investigator, in which case it will continue to be used to the extent it is beneficial.

If a principal investigator considers that the trial subject should be given post-study access to an investigational product, then he/she should give notice thereof to the clinical trial sponsor, which must, in turn, request Digemid's authorisation.

6.4 Are waivers of liability typically utilised with physicians and/or patients and enforced?

No. There are no waivers when harm is suffered as a result of a clinical trial.

The sponsor is obliged to grant compensation for the harm sustained by a trial subject as a result of the use of the investigational product or a procedure followed or intervention undertaken in connection with the research, as is the case for non-therapeutic procedures.

For purposes of the liability regime contemplated in Article 27 of Supreme Decree N° 021-2017-SA, the sponsor must take out an insurance policy covering any harm sustained by a trial subject as a result of his/her participation in the clinical trial. Before the policy's inception, the sponsor must have a financial fund in place to guarantee that the trial subject will receive medical care and treatment at no cost, immediately and in a timely fashion if he/she suffers any adverse effect from the clinical trial. The insurance policy must have coverage in the country. If the insurance policy was taken out with a foreign insurance company, then said company must have a legal representative in Peru. In both cases, this information must be included in the informed consent.

The insurance policy must be kept in full force and effect until the date of filing of the National Final Report. At the end of this period, it must be renewed to the extent a possibility exists that delayed damage could occur, even until the end of the Court proceeding filed, if any, as a result of the damage caused to the trial subject as a direct result of the clinical trial.

6.5 Is there any regulatory or other guidance companies can follow to insulate or protect themselves from liability when proceeding with such programmes?

Supreme Decree N° 021-2017-SA must be followed in order to proceed with the compassionate use programme. In this regulation, the compassionate use programme is known as "post-study access".

It should be mentioned that there is no other guidance that companies can follow to protect themselves from liability when proceeding with such programmes.

7 Product Recalls

7.1 Please identify and describe the regulatory framework for product recalls, the standards for recall, and the involvement of any regulatory body.

The recall procedure for non-pharmaceutical products is regulated in Articles 28 and 29 of Law N° 29571, the Consumer Protection Code, whose Regulation was approved through Supreme Decree N° 050-2016-PCM. In this regard, the national authority in charge of the aforementioned procedure is the National Authority of Consumer Protection of INDECOPI. The mentioned norm states that when a good is offered in the market and afterwards the manufacturer, distributor or providers come to know that said good could create an unforeseen risk or hazard to the safety or health of consumers,

they are under an obligation to: (i) report the incident to the competent authority; (ii) instigate a recall of the goods and services; (iii) exchange or repair the goods; and (iv) inform the consumers as soon as possible regarding the warnings.

On the other hand, regarding pharmaceutical products, medical devices and cosmetics, the recall procedure is regulated in Law N° 29459, Supreme Decree N° 014-2011, and the "Manual of Good Practices of Storage of Pharmaceutical Products, Medical Devices and Sanitary Products in Laboratories, Drug Stores, Specialised Storages and Customs Warehouses", approved through Ministry Resolution N° 132-2015/MINSA. The national authority in charge of the aforementioned procedure is Digemid.

In both cases (non-pharmaceutical products and pharmaceutical products), the supplier is in charge of withdrawing the products where there is any suspicion of defects.

7.2 What, if any, differences are there between drugs and medical devices or other life sciences products in the regulatory scheme for product recalls?

There are no differences.

In Ministry Resolution N° 132-2015/MINSA, the proceeding for withdrawing drugs, medical devices and other life sciences products is established as detailed below:

- A duly documented system for the fast and effective withdrawal of a product from the market in case of any suspicion of defect, or when the defect is already known.
- The products subject to withdrawal shall be stored in a reject/return area until their final destination is established.
- The holder of the marketing registration shall order the withdrawal from the market of products, batches, models, identification series or codes and, if necessary, inform Digemid of the situation.
- The development of the withdrawal shall be monitored and registered and a report of the same shall be written. The registrations shall include the quantities of the distributed and withdrawn products from the market, ensuring the total collection of the goods and the disposition or decision taken related to the same. Said report shall be available when Digemid requests it.

7.3 How do product recalls affect litigation and government action concerning the product?

Regarding non-pharmaceutical products, the recall does not affect litigation and government action concerning the product. This is because, in a recall procedure, the infraction has not materialised but a risk of having any dangerous situation for the consumer has been detected. Under such procedure, once the infraction has been set out, the supplier should commence the corresponding sanction proceeding.

Notwithstanding, applying a correct recall procedure might be considered a mitigating factor for the imposition of a fine.

Regarding pharmaceutical products, actions of suspension and/or cancellation of a marketing authorisation might be ordered, as well as the temporary or definitive closure of an establishment and other security measures according to Article 49 of Law N° 29459.

7.4 To what extent do recalls in the United States or Europe have an impact on recall decisions and/or litigation in the jurisdiction?

Regarding non-pharmaceutical products, to date, we are not aware of any case in which a recall procedure executed in the USA or Europe has had any impact on the decision of the competent authority, where risk to a consumer has arisen.

On the other hand, regarding pharmaceutical products, according to Law N° 29459 and its Regulations, Digemid must publish alerts as a result of national and international drug surveillance when sanitary risk is involved.

7.5 What protections does the jurisdiction have for internal investigations or risk assessments?

There is no legal protection. However, on November 30, 2019, Supreme Decree N° 185-2019-PCM was published, approving the Regulation promoting and supervising the voluntary implementation of regulatory compliance programmes on consumer protection and commercial advertising. The Regulation sets out the components that compliance programmes shall have so that their implementation by a company can be considered a mitigating circumstance at the time of imposing sanctions due to a breach of consumer protection or commercial advertising regulations.

7.6 Are there steps companies should take when conducting a product recall to protect themselves from litigation and liability?

Regarding pharmaceutical products, the guidelines to be followed are detailed in question 7.2 above.

In cases of sanitary risks and/or infringements of law, the fast recall of products from the market and timely information to consumers might be considered mitigating factors.

8 Litigation and Dispute Resolution

8.1 Please describe any forms of aggregate litigation that are permitted (i.e., mass tort, class actions) and the standards for such aggregate litigation.

In the Peruvian judicial legal system, there is no regulation of aggregate litigation as mass tort or class actions. The most similar options to these are diffuse interests, which are covered by a specific regulation under Article 82 of the Code of Civil Procedure. In particular, only the Public Prosecutor's Office, regional governments, local governments, rural or indigenous authorities, and non-profit associations can lodge complaints, and only related to liability for environmental damages or cultural heritage.

However, on the administrative side, the Consumer Protection Code includes provisions about consumers' collective defence. According to these provisions, the exercise of actions for the defence of consumers' rights can be carried out individually or to the benefit of the collective or diffuse interest of consumers. For these purposes, it is understood as:

(i) Consumers' collective interest: these are actions promoted in defence of common rights to a determined or determinable group of consumers that are associated with a supplier and that can be grouped within the same group or class.

(ii) Consumers' diffuse interest: these are actions promoted in defence of an undetermined group of affected consumers.

Duly recognised consumer associations are entitled to file complaints before the Consumer Protection Commission in defence of collective or diffuse interests of consumers or of those who are potentially affected. The Consumer Protection Commission can sanction the defendant and can also order corrective measures, but it cannot award damages. Damages can only be awarded by the Judiciary.

In addition, both the Consumer Protection Commission and consumer associations are able to initiate judicial proceedings in defence of consumers' diffuse interests, requesting the payment of damages to any consumer who has not expressly opted out.

8.2 Are personal injury/product liability claims brought as individual plaintiff lawsuits, as class actions or otherwise?

In the Peruvian legal system, personal injury/product liability claims are brought as individual plaintiff lawsuits. The victim has the right to file a personal injury/product liability complaint due to individual damages suffered. Additionally, if there are cases where more than one person has been damaged in a common situation, they have substantive capacity and can agree to file a personal injury/product liability complaint as a group.

8.3 What are the standards for claims seeking to recover for injuries as a result of use of a life sciences product? (a) Does the jurisdiction permit product liability claims? (b) Are strict liability claims recognised?

There are no particular standards for that kind of claim. A favourable judicial decision depends on the verification in litigation of the elements for the determination of liability, which are: (i) unlawful act; (ii) causality; (iii) wilful misconduct or gross negligence; and (iv) proven damage.

(a) Yes, our legislation permits claims seeking to recover damages for injuries sustained as a result of the use of a life sciences product, but it is not regulated as such in our procedural legal system.

(b) There is no rule about strict liability in our procedural legal system as such but, depending on each case, judges will analyse liability depending on the technical development of the products that people allege caused them injuries.

Then, if the technical development of a certain product has evolved over time, so that its contingencies are publicly known, judges would consider that there is a well-founded right for the victim to receive compensation. However, when a product has not been developed technically, a judge probably will not grant compensation to the victim, in order to protect and incentivise the technical development of that kind of product.

8.4 Are there any restrictions on lawyer solicitation of plaintiffs for litigation?

Prior to litigation, in order to determine the validity of any liability complaint, it is necessary for both parties to obtain an Out-Of-Court Settlement Agreement, according to the Out-of-Court Settlement Law.

8.5 What forms of litigation funding are permitted/utilised? What, if any, regulation of litigation funding exists?

The law does not establish forms of litigation funding. No regulation on litigation funding exists. Litigation expenses are therefore covered by each party. This means each party must pay the fees related to Court filing and official notice, and the costs in order to acquire evidence. At the end of the litigation, the judge may decide that the losing party must pay Court costs and attorney fees to the party who won the case.

8.6 What is the preclusive effect on subsequent cases of a finding of liability in one case? If a company is found liable in one case, is that finding considered *res judicata* in subsequent cases?

The determination of liability in a specific case does not imply automatically that a judge will determine liability in subsequent cases. The Court's analysis in each case is required in order to determine the essential elements of liability, depending on the specific circumstances. Thus, the quality of *res judicata* of a particular judgment cannot be replicated in decisions in other cases.

8.7 What are the evidentiary requirements for admissibility of steps a company takes to improve their product or correct product deficiency (subsequent remedial measures)? How is evidence of such measures utilised in litigation?

In litigation, a variety of evidence that parties could offer may be admitted, including decisions related to subsequent remedial measures. Naturally, the party who offers a decision related to remedial measures as evidence is seeking to convince the judge of its position and reduce or increase the amount of compensation.

8.8 What are the evidentiary requirements for admissibility of adverse events allegedly experienced by product users other than the plaintiff? Are such events discoverable in civil litigation?

The condition of an adverse effect must be determined by a physician and he/she must report such situation to Digemid. Laboratories are also obliged to report to Digemid any adverse events caused by a drug. For the plaintiff, the condition of an adverse event could be proven with the communications made to Digemid by the physician or the laboratory.

8.9 Depositions: What are the rules for conducting depositions of company witnesses located in the jurisdiction for use in litigation pending outside the jurisdiction? For example, are there "blocking" statutes that would prevent the deposition from being conducted in or out of the jurisdiction? Can the company produce witnesses for deposition voluntarily, and what are the strategic considerations for asking an employee to appear for deposition? Are parties required to go through the Hague Convention to obtain testimony?

Depositions are conducted under the rules of the Civil Procedure Code in our jurisdiction. They can serve as evidence

in particular cases, so that the judge can finally issue his/her judgment. Thus, such depositions cannot be used in litigation pending outside the jurisdiction due to the fact that they are evidence in a pending case. Only at the end of litigation can any information from the case be used in other cases, including those outside the jurisdiction, due to its final resolution.

If a particular case is developing in our jurisdiction, witnesses for deposition must testify in front of a domestic judge. Apart from that, there are no particular "blocking" statutes that would prevent the deposition from being conducted in or out of the country.

The company can produce witnesses for deposition voluntarily, but will analyse whether this will contribute to the strategy of the company, and also consider economic and time resources.

Parties are not required to go through the Hague Convention to obtain testimony, in domestic cases.

8.10 How does the jurisdiction recognise and apply the attorney-client privilege in the context of litigation, and with respect to in-house counsel?

As long as an in-house counsel also represents the interests of the company (client), the attorney-client privilege is the same as it would be between a counsel and a legal representative of the company. Thus, the counsel represents the company in litigation and always shares the strategy with the client.

8.11 Are there steps companies can take to best protect the confidentiality of communications with counsel in the jurisdiction and communications with counsel outside the jurisdiction for purposes of litigation?

On the one hand, in cases of communications with counsel in the country, meetings between clients and counsel in order to agree on the strategy at every stage of litigation are recommended, including with the purpose of exchanging information that is confidential for clients.

On the other hand, in case of communications with counsel outside the country, frequent contact through conference calls and email are important. In both cases, counsel have a duty of confidentiality relating to the information of their clients.

8.12 What limitations does the jurisdiction recognise on suits against foreign defendants?

There are no limitations *per se* on recognising suits against foreign defendants. Naturally, as foreign defendants, they need to designate an attorney with sufficient powers to represent clients in Peru. If that does not occur, according to domestic law, the foreign defendant could be declared in default in litigation, with the risk of negative results in future litigation.

8.13 What is the impact of U.S. litigation on "follow-on" litigation in your jurisdiction?

There is no impact of U.S. litigation on private damages actions in the civil Courts, due to the different regulation between the legal systems. In the U.S., the treatment of liability is in accordance with common law and prevention rules, while in Peru the rules for claims of liability are those from the Civil Code and Civil Procedure Code.

8.14 What is the likelihood of litigation evolving in your jurisdiction as a result of U.S. litigation?

In the Peruvian legal system, litigation hardly ever evolves as a result of U.S. litigation, because they are different models with different regulations on liability. A result of U.S. litigation could contribute to academic knowledge in law but will not specifically impact litigation or a future judgment.

8.15 For EU jurisdictions, please describe the status and anticipated impact of the Collective Redress Directive and Product Liability Directive on drug and medical device litigation in your jurisdiction.

This is not applicable in Peru.

Endnotes

1 Please consider that "control" is defined by the Merger Control Law as the possibility of exercising a decisive and continuous influence on an economic agent through (i) property rights or rights for the use of all or part of the company's assets, or (ii) rights or contracts that allow continuous and decisive influence on the composition, deliberations or decisions of the board of directors or other bodies of the company, or directly or indirectly determine the company's competitive strategy.

2 Please consider that "economic group" is defined by the Merger Control Law as two or more economic agents, national or foreign, where one of them exercises control over the others, or when the control over the economic agents is exercised by a natural person acting as a unit of decision.

3 The applied exchange rate was calculated using the Peruvian Central Bank's most recent information as instructed by INDECOPI and must be updated by the end of every month.

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Our Life Sciences & Healthcare group offers a unique multidisciplinary approach. Our in-house team of pharmacists allows us to develop strategies and propose innovative and appropriate solutions to conflicts and critical situations by means of rights to petition, infringement actions, appeals, oppositions to sanitary registry requests, data protection in trials, and maintaining due confidentiality of dossiers.

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