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1. What are the main laws governing the manufacture and sale of pharmaceuticals in the jurisdiction?

The primary legislation governing the manufacture and sale of pharmaceuticals in Turkey is Law No. 1262 on Pharmaceuticals and Medicinal Preparations (Law No. 1262). The secondary legislation, includes the Regulation on the Licensing of Medicinal Products for Human Use (Licensing Regulation), the Regulation on Manufacturing Plants of Medicinal Products for Human Use , the Regulation on the Promotional Activities of Medicinal Products for Human Use (Promotion Regulation), the Regulation on Packaging Information, Inserts and Tracing of Medicinal Products for Human Use (Packaging Regulation), the Regulation on the Classification of Medicinal Products for Human Use and the Regulation on the Safety of Medicinal Products.

Law No. 6197 on Pharmacists and Pharmacies (Law No. 6197), Law No. 984 on Pharmaceutical Enterprises and Stores Selling Toxic and Active Chemical Materials Used in Arts and Agricultural Businesses (Law No. 984) and their secondary legislation, include the Regulation on Pharmacies and Pharmacists (Pharmacy Regulation) and the Regulation on Pharmaceutical Warehouses and Products Located in Pharmaceutical Warehouses (Pharmaceutical Warehouses Regulation) include other notable rules on the dispensing and sale of pharmaceutical products.

2. Are there any significant differences in this area of law in this jurisdiction compared to jurisdictions like the US and EU?

It is fair to say Turkish pharmaceuticals legislation follows EU legislation trends. Many important subjects under the pharmaceuticals legislation (such as licensing, clinical trials, pharmacovigilance, packaging and labelling) are parallel to the EU legislation with particular local differences. There are also several local associations of pharmaceutical companies who are associated with the global federations of pharmaceutical industries and associations. These local associations publish guidelines and codes of practice. Although these guidelines and codes of practice are not part of the Turkish pharmaceutical legislation, and so are not binding on companies, pharmaceutical companies who are affiliates with these associations show the utmost care to ensure compliance with those rules in their practice. Industrial practice is therefore mostly in line with global standards as well.

One major difference in Turkey compared to the EU and US is that the advertising and promotion related rules are much stricter and are subject to the detailed procedures and surveillance from authorities. Patent protection and data exclusivity is limited and there is no marketing exclusivity in Turkey.

3. Who are the main regulators governing the licensing, the sale, or the manufacture of pharmaceuticals in this jurisdiction?

The Health Ministry (MoH) is the main Government body governing the licensing, sale, or manufacture of pharmaceutical products in Turkey. It oversees the pharmaceutical sector through the Turkish Pharmaceutical Product and Medical Device Agency (PPMDA), which is authorised to regulate all aspects of pharmaceuticals including licensing, manufacturing, sales, import/export, pricing, promotions and clinical trials. In addition to its regulatory powers, the PPMDA is also authorised to supervise the actors in the market, monitor compliance with the legal requirements, conduct inspections and impose sanctions such as the suspension or cancellation of licenses and/or administrative fines.

In Turkey, the Turkish state is the main buyer in the pharmaceutical sector because of the broad coverage of public health insurance. Although it does not regulate the licensing, sale, or manufacture of pharmaceuticals, the Social Security Institution is also a notable regulatory actor as it regulates public healthcare expenditures and the reimbursement regime.

4. When new drugs are created, which agency is responsible for giving the permission for the sale/manufacture in this jurisdiction?

The PPMDA under the MoH is responsible for giving permission for the sales and manufacturing of new pharmaceutical products.

5. What steps must a pharmacist take before being allowed to practice in this jurisdiction?

Anyone who wants to be a pharmacist must fulfil the conditions under Law No. 6197. They must:

- -be a Turkish citizen,

  -be a graduate of a Pharmacy Faculty from a Turkish university or a foreign university, provided the professional aptitude is proven before a jury or certain examinations are taken if transferring from a foreign university,

  -have a diploma certified by the MoH,

  -not fall under the prohibitions listed under Law No. 6197, which include:

  - (i) being jailed for five years or more for committing a crime through wilful misconduct, being jailed for committing a crime against the security of the state, a crime against the constitutional order and its operation, embezzlement, extortion, bribery, theft, fraud, forgery, abuse of trust, fraudulent bankruptcy, collusive tendering, fraud during discharge of contractual obligations, acquittal of criminal assets, or smuggling,

    (ii) being disqualified from conducting pharmacy practices in another jurisdiction, and

    (iii) having a disease or visual impairment (blindness) obstructing the ability to perform the profession.

If a pharmacist wants to open their own independent pharmacy, in addition to fulfilling the criteria above, they must also:

- -be registered before a regional chamber of pharmacists,

  -have worked as an assistant pharmacist in a pharmacy under an employment contract for at least one year, and

  -be authorised/placed to open a pharmacy in a designated district after an the evaluation of the MoH.13.

6. What are the requirements involving ownership and licensing of a pharmacy in this jurisdiction?

As a main principle, only qualified pharmacists (i.e., pharmacists fulfilling the requirements under Law No. 6197 can open an independent pharmacy in Tukey once they obtain a license issued by the regional directorate of the MoH (Regional Directorate) and approved by the governorship where the pharmacy is located. Pharmacists are not allowed to open more than one pharmacy.

A new central placement system has also been introduced with new requirements for opening a pharmacy in the amendments made to Law No. 6197 in 2012.5 Under this new system, the details of which are regulated under the Pharmacy Regulation, the number of independent pharmacies to be opened are limited based on the population of each district. The quantity of pharmacies in a district are calculated to ensure there is at least one pharmacy for every 3,500 people living in the district. The criteria concerning the number of residents is disregarded for districts where there are no pharmacies. When determining the number of pharmacies, the socio-economic status of the district may also be taken into consideration.

The MoH has the power to decide the number of pharmacies to be established in each district (if any) and to authorise pharmacists to open a pharmacy in a specific district by evaluating their service grades.

The PPMDA, under the MoH, determines the districts where a pharmacy can be opened and the number of pharmacies to be opened and announces this information three times a year on its official website. Pharmacists wishing to open an independent pharmacy in the announced districts apply to the PPMDA through an online platform by submitting the required documents listed under the Pharmacy Regulation within 30 days of the announcement date. During this application, pharmacists also submit a list of their preferred locations for their pharmacy among the locations announced by the PPMDA. This list can include up to 25 locations chosen by a pharmacist.

There is also a scoring system to calculate the service grades of pharmacists. Each pharmacist is graded by the PPMDA based on their length of service and the previous locations/districts they worked as pharmacists. On completing the application process explained above, the PPMDA evaluates the service grade of each pharmacist and those who have scored the highest are given the chance to open pharmacies in the locations they chose in their application to the PPMDA.

Once the placement process is complete, the PPMDA announces the placement list on its website and notifies the Regional Directorate. Pharmacists who have been authorised to open a pharmacy should apply to the Regional Directorate by submitting the additional documents listed under the Pharmacy Regulation within 90 days of the announcement date.

In this step, the store/building to be used as a pharmacy is also evaluated to ensure it meets the conditions under the Pharmacy Regulation. The requirements are mostly in relation to the physical conditions, security and the accessibility of the premises. The regional chamber of pharmacists makes the evaluation and prepares a report based on its evaluations. The Regional Directorate conducts an onsite inspection to approve the report prepared by the regional chamber of pharmacists.

At the request of the Regional Directorate, the regional chamber of pharmacists also makes an investigation to detect any collusion and prepares another report within 15 business days.

Once it has been confirmed there are no restraints for opening up a pharmacy and once all of the required fees have been paid, the Regional Directorate issues a license to open a pharmacy. The license must also be approved by the regional governorship and both the PPMDA and the Turkish Pharmacists Association must be notified.

7. What rules govern the dispensing of prescription of drugs in this jurisdiction?

There are several different ways to dispense pharmaceutical products in Turkey.

The most common way to dispense pharmaceutical products is to sell the products to patients in pharmacies who provide the pharmaceutical products from pharmaceutical warehouses. In this way, pharmaceutical warehouses and pharmacies are the two main actors in dispensing pharmaceutical products in Turkey. The main governing rules are Law No. 984, the Pharmaceutical Warehouses Regulation, Law No. 6197 and the Pharmacy Regulation.

Only licensed pharmaceutical products can be dispensed and sold to patients. Pharmaceutical warehouses, who should hold the required license and fulfil the requirements under the Pharmaceutical Warehouses Regulation, buy products from licensed manufacturers in Turkey or marketing license holders who import pharmaceutical products from manufacturers abroad by obtaining the required licenses.

The licensed pharmaceutical products are then sold and delivered to local pharmacies by the pharmaceutical warehouses. During this process, pharmaceutical warehouses are expected to fulfil requirements under the Good Distribution Practices Guidelines on Pharmaceuticals and Products Stored in Warehouses.

As the final step to dispense pharmaceutical products, pharmacies sell the drugs to patients with or without a prescription, depending on the type of drug. Under Article 28 of the Pharmacy Regulation, only prescriptions issued by doctors and dentists may be accepted by pharmacists (prescriptions issued by veterinarians are accepted only for veterinary medicinal products). Prescriptions are then signed and stamped by the pharmacists, the responsible manager, or the assistant pharmacist.

There are also special requirements regarding the dispensing of pharmaceutical products which contain narcotics or psychotropic substances. Similar to other pharmaceutical products, pharmaceutical products which contain narcotics or psychotropic substances can be manufactured or imported by obtaining a license. However, the number of products being imported or sold are strictly monitored. Pharmaceutical warehouses must collect a signature from the pharmacist or assistant pharmacist on the relevant delivery forms when delivering pharmaceutical products which contain narcotics or psychotropic substances and must keep those records for five years. They must also inform the PPMDA of the number of products they sold and keep these on a monthly basis.

These pharmaceutical products can only be sold to patients if they are prescribed with special prescriptions. Pharmacists used to keep a copy of these prescriptions as they were required to submit these to authorities and the original copy of the prescription was not returned to the patients. However, from April 2018, the PPMDA introduced a new online software (named Coloured Prescription System) where doctors issue special prescriptions and pharmacists record the actions (including purchases from the warehouse, sales to patients, returns, destruction, etc) relating to pharmaceuticals subject to a coloured prescription and prescription medications which are under the surveillance of the PPMDA.

As an alternative dispensing method, pharmaceutical warehouses, manufacturers, or marketing license holders who import licensed pharmaceutical products to Turkey may also sell pharmaceutical products to hospitals by participating in their tender, which are then used for the medical treatment of patients in hospitals.

Although not as common as the other dispensing methods explained above, according to Article 11 of the Pharmaceutical Warehouses Regulation, dispensing a pharmaceutical product under the named patient programme is also possible. Accordingly, when a patient needs a pharmaceutical product which is either not licensed or not commercially available in Turkey, then the pharmaceutical product can be supplied to the patient through the Turkish Pharmacists Association on a prescription for the pharmaceutical product issued by a physician. The PPMDA's prior approval for a specific patient may also be needed depending on whether the medicinal product or substances are listed in the active substance list in the Foreign Pharmaceuticals List published by the PPMDA. The PPMDA's Guideline on the Procurement of Medicines Abroad and the Use of Said Medicines explains the details of the rules and procedures to be followed in detail.

Dispensing pharmaceutical products under the compassionate use programme is another but rare method of dispensing pharmaceuticals in Turkey. According to the Guidelines on the Compassionate Use Programme, if a patient suffers from a serious, urgent, or life-threatening disease and their treatment with existing licensed products has failed and they cannot participate in clinical trials, then pharmaceutical products which are not licensed in Turkey can be imported. This programme is again subject to the approval of the PPMDA of an application made by a physician for a specific patient. The application documents listed under these guidelines, which also includes a letter of undertaking from the physician, must be submitted for evaluation. The programme only applies for drugs whose Phase-II trials (at least) have been completed and whose Phase-III trials have started. No fees can be charged for procurement of these medicinal products and procurement of the product should continue as long as the patient benefits from this product, which is recorded under quarterly reports prepared by the physician, which are submitted to the PPMDA.

Pharmaceutical Track and Trace System

Apart from the above, as an important part of the dispensing process, the Pharmaceutical Track and Trace System” (ITS) was also introduced in Turkey in recent years (for the avoidance of any confusion, it is a different system to the Coloured Prescription System) The system is designed to track the location of every pharmaceutical product unit to ensure the reliable supply of products to patients. Each licensed medicinal product placed on the market has a unique data matrix (also referred to a square-code) and each actor in the process (including license holders, pharmaceutical warehouses, pharmacies, etc) are under the obligation to record each of their actions (e.g sales, returns, exports, transfers, theft, expiration of shelf life, destruction, etc) in the ITS. (Documents evidencing the records made in the ITS should also be kept for five years). If information uploaded to the ITS is not consistent with the information chain in the ITS, the system rejects the application. Accordingly, the PPDMA can monitor each step of the life cycle of the pharmaceutical products starting from the manufacturing or import phase until they are sold to patients or destroyed and the risk of selling fraudulent medicinal products, thefts, or barcode scams are significantly reduced.

8. Are there rules on the pricing on prescription drugs in this jurisdiction?

Yes, there are rules on the pricing on pharmaceutical products in Turkey. These pricing rules are substantially regulated under decrees. The last Decree on the Pricing of Medicinal Products for Human Use (Pricing Decree) was published in the Official Gazette on 24 February 2017 and entered into force on the same date. The Communique on the Pricing of Medicinal Products for Human Use (Pricing Communiqué) also regulates further details on the pricing system in Turkey.

Under the Pricing Decree, the MoH set up a reference price system. In this reference price system, the real source price, which is calculated by a method explained in detail in the secondary legislation, is taken into account to determine the prices of pharmaceutical products. Accordingly, the prices are set by determining the lowest real source price among the reference EU countries (France, Spain, Italy, Portugal, and Greece). Prices can also be set by taking into account the lowest price in the country of import (other than the countries indicated above) or the country of batch release. The active substance and its form or dosage are also taken into account when determining the real source price.

The source price of a non-price protected reference product is 100% of the real source price until its generic enters the market. In the event of a generic entering the market, the source price of the non-price protected reference product is reduced to 60% of the real source price. Non-price protected generic products can be priced up to 60% of the real source price. Price protected generic products can be priced up to 80% of the real source price. Certain exceptions to the above rules were introduced for specific types of pharmaceutical products.

In addition to the above, the Price Determination Commission also determines a fixed euro exchange rate to be used in pricing calculations each year. According to the Pricing Decree, the exchange rate to be calculated for determining the price will be 70% of the previous year's average EUR/TRY exchange rate as announced by the Turkish Central Bank. The pegged exchange rate to be used in 2020 was determined and announced as 3,8155 Turkish Lira on 18 February 2020.

Following price determination through the reference pricing system, certain warehouse and pharmacy profit margins and the relevant taxes are added to calculate the retail price of a product.

The pricing of a product is commonly determined during the licensing process. Yet, any subsequent changes must be notified to and evaluated by the PPMDA in line with the Pricing Communique.

9. What rules apply when importing controlled substances and prescription drugs into the country?

As a general rule, the import of pharmaceutical products to Turkey can only be made by license holders after obtaining a marketing license from the PPMDA for the specific pharmaceutical product. (The rules differ for special cases such as importing prescription drugs under the named patient programme or compassionate use programme. Under the Communique on the Import of Substances Under the Control of the Health Ministry, the importer must obtain a control certificate by applying to the MoH (through the PPMDA) and submitting the application documents and information listed under the Communique. Once the import process is complete, the bill of entry issued by the customs authority should be submitted to the MoH within 15 days of the completion of the customs process.

The import of pharmaceutical products containing narcotic or psychotropic substances is subject to a stricter set of rules. Under Law No. 2313 on the Control of Narcotic Substances (Law No. 2313), the import of narcotic substances is subject to the MoH's permit for import. The law also says the MoH must send a copy of the import license to the relevant authority of the country from which the narcotic substances/pharmaceuticals containing narcotic substances were sent.

The Regulation on Controlled Chemicals (Controlled Chemicals Regulation) also requires a permit to be obtained from the MoH in order to import chemicals which are or may be used to manufacture any narcotic or psychotropic substances . The MoH conducts a detailed investigation and evaluation, which may also include onsite audits, for applicants seeking an import permit for controlled chemicals for the first time.

In addition to obtaining specific permits for importing pharmaceutical products containing narcotic or psychotropic substances and/or controlled chemicals, under the Communique on the Import of Substances Subject to Specific Approval from the Health Ministry, the importer must also obtain a control certificate by applying to the MoH (through the PPMDA) and submitting the application documents and information listed under the Communique. Once the import process is complete, the bill of entry issued by the customs authority will be submitted to the MoH within 15 days of completion of the customs process.

10. What are the penalties for contravention of these import rules?

Under Article 19 of Law No. 1262, importing pharmaceutical products without a license is considered an act of smuggling and the people involved should be punished in line with Law No. 5607 on Anti-Smuggling (Law No. 5607). Under Law No. 5607, goods imported without a license are considered smuggled goods and will be confiscated. Offenders who have committed the crime of smuggling are subject to jail for five years, the length of which may vary depending on the specifics of the case and a judicial fine of up to 10,000 days. People knowingly buying, selling, marketing, transporting, or hiding the smuggled good are also considered to have committed a crime and they will be jailed for up to three years and a judicial fine of up to 5,000 days.

It is not possible to clear any pharmaceutical products containing narcotic or psychotropic substances from customs without obtaining approval from the MoH. However, importing (or any attempts to import) pharmaceutical products containing narcotic or psychotropic substances without approval constitutes a criminal offence under the Turkish Criminal Code . According to Article 20 of Law No. 2313, any narcotic substances which are imported or attempted to be imported without a license will be confiscated as evidence and the issue will be immediately notified to the public prosecutor to initiate a criminal lawsuit. Under Article 188 of the Turkish Criminal Code, importing narcotic and/or psychotropic substance without a license is considered a criminal offence which will see perpetrators jailed for between 20 and 30 years and a judicial fine of between 2,000 and 20,000 days. If the crime is committed by a legal entity, security measures prescribed by the law (e.g cancellation of licenses) are applied.

With respect to the import of controlled chemicals, under the Controlled Chemicals Regulation, if it is realised the import permit/ or license holder no longer fulfils the requirements of the import permit or license or uses the controlled chemicals for a purpose other than that declared in the permit application, then the permit or license can be suspended or cancelled.

11. Do rules on import of controlled substances and prescription drugs come into play when drugs are brought into the country having been purchased overseas on the internet or having been brought into the country in transit?

The import of pharmaceutical products and narcotic or psychotropic substances are subject to strict rules and only license holders are authorised to import these products. Under Law No. 6197 and the Pharmacy Regulation, certain medicinal products (including human medicinal products, licensed herbal medicinal products, special dietary food and infant formulas for specific purposes) can be sold exclusively at pharmacies and the sale of these products through the internet or other electronic platforms is strictly prohibited. Additionally, there are special programmes (such as the named patient programme and the compassionate use programme) to accommodate the need to provide pharmaceutical products from abroad and these programmes are also subject to certain rules and approvals. The PPMDA also emphasised the importance of following

procedures in the legislation while providing medicinal products from abroad and the possible administrative actions and/or penalties which may be triggered for non-compliance under Circular No. 24931227. With this in mind, purchasing pharmaceutical products online from overseas and bringing them to Turkey may be construed as circumventing these rules and procedures.

In parallel with the restriction on selling pharmaceutical products online, authorities can also block access to a website when they detect an advertisement or sale of pharmaceuticals. Therefore, if a prescription drug is purchased overseas on the internet, delivered to Turkey and detected by the authorities, it is highly likely access to the relevant website will also be restricted in Turkey.

Someone travelling to Turkey may bring a reasonable amount of prescribed pharmaceutical products solely for their personal use by declaring the necessary documents (health reports, doctor reports, prescriptions, etc) to the customs authority.

12. What are the main laws protecting intellectual property in the pharmaceutical industry? Are there any significant allowances in the way things work compared to jurisdictions such as the US and EU?

The main law regulating intellectual property in the pharmaceutical industry in Turkey is Law No. 6769 on Industrial Property. The legislation and practices of the Turkish Patent and Trademark Institution (TPTI) are also parallel to the practices of the World Intellectual Property Organisation, European Patent Office and European Union Intellectual Property Office.

In order to register a patent or trademark, an application to the TPTI must be made under the process explained in Law No. 6769 and the guidelines of the TPTI. As Turkey is a party to international treaties on intellectual property, it is also possible to apply through the World Intellectual Property Organisation, European Patent Office, and European Union Intellectual Property Office for an international or EU patent or trademark and extend the application to cover Turkey, which is mostly preferred by the pharmaceutical companies particularly for patent applications.

A material difference in intellectual property as it relates to the pharmaceutical industry in Turkey is that patent protection lasts 20 years from the date of filing the application and the subject of the patent becomes public property after this period has expired. Turkish law does not allow for the renewal of a patent or for the extension of the protection period, such as granting supplementary protection certificates in the EU.

Another material difference is that while patent protection prevents the entry of generics into the market, due to an exception regulated under Law No. 6769 , marketing authorisation applications or other experimental activities including the test and trials to obtain marketing authorisation do not fall within the scope of patent protection. Therefore, it is not possible to prevent generic marketing authorisation applications or other activities conducted by generic manufacturers for the purposes of filing such applications. As an alternative solution for protection, the data exclusivity concept under the Licensing Regulation applies. Under the Licensing Regulation, the data exclusivity period lasts for six years commencing from the marketing authorisation date. However, the data exclusivity period is also linked and limited to the patent protection period applicable in Turkey and so the period ends if the patent protection expires. During the data exclusivity period, no abridged application can be made using clinical data obtained from the clinical trials performed during the marketing authorisation application of the original pharmaceutical product. However, as there is no marketing exclusivity in Turkey, generic companies can make abridged applications to obtain marketing authorisation following the expiration of the data exclusivity period.

13. Are health supplements, vitamins or other non-prescription drugs regulated in any particular way?

In principle all pharmaceutical products, including supplements, vitamins and all non-prescription drugs, are regulated by the MoH under the MoH's legislation. However, products which fall within the scope of the food supplement definition under Law No. 5996 on Veterinary Services, Plant Health, Food and Feed (Law No. 5996) are subject to the law (and its secondary legislation) and accordingly, are regulated by the Agriculture and Forestry Ministry (MoAF) rather than the MoH.

Law No. 5996 defines food supplements as 'products prepared in the form of capsules, tablets, powder packets for single use, liquid ampoules, dropping bottles or other liquid and powder forms of nutritional elements such as vitamins, minerals, proteins, carbohydrates, fibres, fatty acids and amino acids, or plants, substances of herbal or animal origin, bioactive products or other similar products with nutritious and physiological effects, or their combinations prepared in specific doses in order to supper daily nutrition'. Therefore, health supplements and vitamins falling within the scope of these definitions are subject to Law No. 5996 and its secondary legislation, including the Regulation on Import, Manufacturing, Processing, and Supplying Food Supplements (Food Supplements Regulation), whereas, pharmaceutical products (including prescription and non-prescription pharmaceutical products) are subject to Law No. 1262 and its secondary legislation.

The manufacturing, import, processing, and marketing of both pharmaceutical products and food supplements are subject to licensing and approval from their respective regulatory authorities. However, there are several differences in the licensing and approval processes. First, the regulatory authorities granting authorisation are different. The regulatory body for food supplements is the MoAF, while the MoH oversees pharmaceutical products.

Second, applications for manufacturing and marketing authorisation for food supplements are easier and shorter and require fewer conditions compared to applications for manufacturing and marketing authorisation for pharmaceutical products. An application is made to the provincial directorate of the MoAF with the documents listed in the Annexes of the Food Supplements Regulation. These documents and the information provided are limited compared to the documents and information provided to the PPMDA for license applications of pharmaceutical products. The MoAF evaluates the application by reviewing the documents submitted and it may also conduct an onsite inspection. If the MoAF determines the information

and documents provided are sufficient, then it provides a permit and grants a specific approval number for the food supplements subject to the permit application, which should be included in the information on the packaging of the product.

Once the MoAF has approved a product, the applicant must manufacture, import, process and market these products. The applicant's enterprise should also be registered as a food enterprise in line with the Regulation on Recording and Permit Applications for Food Enterprises and must obtain an enterprise number, which should also be included in the information on the packaging of the product.

The approved food supplements can be marketed in the importer, manufacturer, and/or operator's own salesroom, food enterprises on the market and/or in wholesale warehouses, or on websites declared by the operators or by the direct sellers who contracted the operators.

Labelling food supplements is subject to the Turkish Food Code Regulation on Labelling and Informing Consumers, rather than the Regulation on Packaging and Labelling, and so, the mandatory information to be included on the label and the package are different and more limited than the information which should be included for pharmaceutical products. As a major rule, the label on a food supplement should not include any wording or statement which may give the impression the supplement is directly or indirectly good for human health, has a positive or curing effect against any illnesses or symptoms, or that the product may protect the user from illnesses, unless approval was obtained from the PPMDA first. It should be clearly stated on the packaging that the product is a food supplement and is not a pharmaceutical product. To avoid giving this impression, the names and brands of pharmaceutical products licensed by the MoH should not be used for food supplements. In addition, during the permit application phase, the MoAF requests applicants submit a statement undertaking that the trademark used for the food supplement subject to their application is not a trademark of a pharmaceutical product licensed by the MoH.

Another important difference between food supplements and the pharmaceutical products is that the advertisement of food supplements is permitted. However, it should be ensured these advertisements do not lead to food supplements being perceived as pharmaceuticals and the principles explained above for labelling food supplements should be adhered to.

14. Are there any significant rules on the packaging of drugs in this jurisdiction?

The Packaging Regulation sets out the procedures and requirements related to the information which must be included on labels, packages (both outer and inner packaging) and medicinal product leaflets. (The TPPMDA also issued the Guideline on Packaging Information Instruction Manuals for Medicinal Products to provide further details of the packaging requirements, which has been updated multiple times to evolve with practical needs.)

Although there are several differences between the information to be included in the outer packaging and inner packaging, among others, the following information must be included in the packaging of a medicinal product:

- -Name, strength, and pharmaceutical form of the medicinal product. If necessary, the name on the license or permit approved by the PPMDA should be written, indicating if it the product is intended for babies, children, or adults. The common name is indicated if the medicinal product contains up to three active substances.

  -Unit amount, mode of administration and weight or volume of the active substances.

  -Number of units (tablets, ampoules, or bottles) in the package and the volume and weight or dosage of active substances in pharmaceutical form.

  -Names of excipients such as colourants, preservatives, antioxidants, flavouring substances and alcohol.

  -List of excipients known to have certain effects.

  -Application methods and instructions (if necessary).

  -A special warning stating the medicinal product must be stored away from children and in its package, as well as other special warnings (as necessary).

  -Special warnings stating 'do not buy cut or opened packages', 'read the package insert before use', 'contact your physician if you notice any side effects'.

  -Storage conditions of the medicinal product.

  -A special warning regarding the disposal of unused products or waste products and the appropriate collection system if necessary.

  -Recyclable symbol, number, and abbreviation of the package type.

  -Name and address of the manufacturer and authorisation/permit holder.

  -Name and address of the manufacturing facility.

  -Medicinal product's authorisation or permit number.

  -Medicinal product's batch number and expiration date.

  -Medicinal product's expiration date.

  -Instruction for users, if necessary.

  -Applicable warnings.

  -Whether the medicinal product is subject to a prescription.

  -A barcode.

- A data matrix/square code (for the ITS system).

-Information on pricing (optional).

-Information on a measuring cup is included (if applicable).

The outer and inner packaging of a product should be submitted to and approved by the PPMDA in the license application. Any amendments in the packaging triggers an additional application to the PPMDA.

In addition, the Packaging Regulation requires each human medicinal product to include a package leaflet, the minimum content of which is also listed under the Packaging Regulation.

The information on the outer and inner packaging and the leaflet of a product should be written in plain language to allow patients to easily read and understand the content. The information included in the packaging must also be in Turkish, but, if necessary, information in any official language of an EU member country can also be added, provided the information in all languages is identical and the PPMDA's approval has been obtained.

15. Are those involved in virtual medicine allowed to prescribe or sell drugs to patients?

The concept of virtual medicine is not regulated or classified as an institution under the Turkish pharmaceutical and healthcare legislation. Under Law No. 1219 on the Mode of Execution of Medicine and Medical Sciences, physicians have the sole authority for treatments and prescribing medicine.

As a general principle, in order for a physician to prescribe medicine, the patient has to register for the treatment within a healthcare institution in person and they either receive treatment or be forwarded to a higher healthcare institution. The diagnosis is done face to face by physicians and medicine can only be bought from the pharmacies.

As strict rules apply to prescribing or selling medicinal products and virtual medicine is not clearly approved, it can be construed those involved in virtual medicine are not allowed to prescribe drugs to patients.

With respect to selling drugs to patients, it is regulated clearly under Law No. 6197 and the Pharmacy Regulation which certain pharmaceutical products (including human medicinal products, licensed herbal medicinal products, special dietary food and infant formulas for specific purposes) can be exclusively sold at pharmacies. This regulation also prohibits selling pharmaceutical products through the internet or other electronic platforms. It can therefore be construed those involved in virtual medicine are not allowed to sell pharmaceutical products to patients.

16. Are there any rules governing the advertising of drugs?

Advertising pharmaceutical products is strictly regulated in Turkey. The main pieces of legislation regulating these advertisements are Law No. 1262 and the Promotion Regulation.

Advertising pharmaceutical products, with or without prescription to the general public is strictly forbidden. However, the legislation allows pharmaceutical companies to promote their licensed products to healthcare professionals subject to the requirements and exceptions under the Promotion Regulation.

According to the Promotion Regulation, promotion activities can be conducted by providing promotional material such as printed materials relating to the products, making in person visits to physicians, dentists and pharmacists by medical representatives (minimum requirements of which are also regulated under the Promotion Regulation) and organising scientific or product promotion meetings. It is also possible to provide physicians, dentists and pharmacists free samples subject to the rules under the Promotion Regulation, as long as the medicinal product does not include a controlled substance and/or is not listed by the PPMDA as one of the products whose samples cannot be distributed.

The Promotion Regulation also introduced detailed rules on promotional activities. Article 6 of the Promotion Regulation lists the general principles to be followed for promotional activities. Among others, the information in the promotion material must comply with the information provided to and approved by the PPDMA. The promotion must also provide objective, informative and factual medical data in a way which allows healthcare professionals to form their own opinions about the medicinal product. The promotional activities must not encourage unnecessary use of a medicinal product. No benefits, whether in cash or in kind, should be offered or promised to a healthcare professional while the products are being promoted. Promotions cannot involve sweepstakes, lotteries, or similar schemes. If a healthcare professional takes part in the promotional activity of a medicinal product, permission should be obtained from the MoH.

In addition, the Promotion Regulation details the requirements for organising scientific or product promotion meetings, including the dates for these meetings (e.g. restrictions on the dates of the meetings to be convened in ski resorts and seaside resorts), certain topics to be added to the agenda of the meeting (e.g. publishing the presentation of the PPMDA on pharmacovigilance activities to raise awareness, having a session on the rational using of drugs relevant to the topic of the meeting in at least 60% of all meetings exceeding six hours organised by a license holder in one year), limitations and restrictions on healthcare professionals which may participate in the meeting sponsored by a license holder (e.g. only healthcare professionals with a profession relevant to the subject of the meeting can participate in the meetings under the sponsorship of a license holder, except where a healthcare professional participates in a meeting as a speaker or a researcher presenting a paper; a healthcare professional can benefit from the sponsorship up to four times in one calendar year and only two of these sponsorships may be provided by the same license holder and only two of these sponsorships can be used for a meeting abroad. Sponsorship is provided to the organisation holding the meeting and not directly to an individual). There are also limitations on the expenses the license holders can sponsor (e.g. except for speakers, the travel and accommodation expenses of the healthcare professionals cannot be reimbursed by a license holder) and notification requirements (i.e. the license holders should inform the PPMDA about the details of the scientific or product promotion meetings they organise or sponsor and the healthcare professionals they sponsored).

Although they are not part of the binding legislation in Turkey, industry associations in Turkey, such as the Association on Research-Based Pharmaceutical Companies (AIFD), the Pharmaceutical Industry Association of Turkey and the Pharmaceutical Manufacturers Association of Turkey, have their own Codes of Promotional Practices which compliment these applicable rules. It is worth saying the AIFD principles are very similar to the rules of the International Federation of Pharmaceutical Manufacturers & Association. Although these are non-binding regulations, reputable pharmaceutical companies who are affiliates with these associations take the utmost care to ensure compliance with those rules.

17. What is the main legislation governing legal possession of controlled substances?

In Turkey, the main legislation governing the legal possession of narcotic and psychotropic substances is Law No. 2313. Chemicals which are or may be used to manufacture any controlled substance are also regulated under the Controlled Chemicals Regulation.

According to Law No. 2313, the import, export, purchase, sale, production and circulation of narcotic and psychotropic substances specified under Law No. 2313 and the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances are subject to the permission of the MoH. The controlled substances or pharmaceutical products containing controlled substances which are manufactured or imported based on a license issued by the MoH can be sold by pharmaceutical warehouses to pharmacies or authorised laboratories. These products can be sold to the public only in pharmacies after delivery of a special type of prescription issued by an authorised physician. The dispensing process and each step of the process is strictly recorded and monitored.

According to the Regulation on Controlled Chemical Substances, only duly authorised importers may import and sell controlled chemical substances. It is crucial the substances are only used for the purposes declared in the documents submitted to the MoH with the application for the import permit. If the controlled chemicals are sold or transferred to a third party, the transfer or sale is also recoded under specific type of forms published by the MoH and related document are kept for a term of five years to be submitted to the MoH at their request or in case of an inspection.

18. Are laboratories carrying out research with drugs required to be registered? If so, who is the regulator and what are the main steps?

Laboratories carrying out research on drugs may be subject to different registration and/or license requirements depending on the nature of their research. It is common for laboratories involved in tests on animals in pre-clinical trial phase and tests during the clinical trials.

Under the Regulation on the Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes (Regulation on the Protection of Animals Used for Experiments), institutions using animals in test and trials must be registered with the MoAF and are required to obtain a series of permits. The institution must first file an application with the regional directorate composed of the documents listed under the Regulation on the Protection of Animals Used for Experiments to obtain approval for the premises being used. After the regional directorate's review of the application documents and after an on-site visit has been made, a report is prepared. Once the premises has been approved, the local governorship issues a permit for establishment valid for a term of one year, which may be extended for another year. On the completion of the establishment, another application must be made to obtain an operation permit by submitting documents concerning the institution and the authorised personnel. The application is evaluated based on the documents submitted and on an onsite visit (if necessary) and an operation permit is granted for 10 years.

Laboratories may also take part in clinical trials. Clinical trials can be conducted by a qualified research team in university training and research hospitals (including military training and research hospitals), certified training and research centres and public training and research hospital associations.

Laboratories carry out research on drugs through clinical trials. Under the Regulation on the Clinical Research of Pharmaceuticals and Biological Products (Clinical Trials Regulation), clinical trials are preferably conducted on sites which are designed for clinical trials at centres for health practice and research established in universities (including military training and research hospitals), approved centres for research and development which are part of universities, and the MoH's training and research hospitals which are suitable for and possess the appropriate staff, equipment and laboratory means to ensure the safety of research volunteers and to properly conduct and monitor clinical trials and appropriate emergency care should it be necessary. The Good Clinical Practice Guidelines and the Phase I Clinical Trial Centres Guidelines provide further details on the requirements for research centres, members and leaders of the research teams. However, these Guidelines are silent on any specific registration requirement for laboratories of these healthcare institutions conducting clinical trial (it should be noted the above listed institutions are already subject to the MoH's permits and surveillance under their specific applicable legislation and the clinical trials are also subject to a separate permitting process). Medical laboratories may also need to be involved in clinical trial processes for conducting the necessary medical tests on the trial subject candidates and trial subjects in the following phases of the clinical trial. These medical laboratories are subject to a registration requirement. According to the Regulation on Medical Laboratories, medical biochemical laboratories, medical microbiology laboratories, and medical phatalogy laboratories must obtain a license from the MoH.

19. Are there any specific health and safety rules governing the operation of laboratories handling dangerous materials and disposal of waste substances?

There is no piece of legislation specifically regulating the health and safety rules on the operation of laboratories handling dangerous materials. Therefore, the provisions of Law No. 6331 on Occupational Health and Safety “Law No. 6331) and its secondary legislation apply to these laboratories.

Under the health and safety legislation, enterprises engaging in activities utilising dangerous materials are classified as 'very hazardous' workplaces and are subject to the relevant requirements under the law. Accordingly, among other obligations imposed by Law No. 6331 and its secondary legislation, employers in these workplaces must appoint an occupational physician and an occupational safety specialist holding a Class-A expertise certificate. These services can be provided by the personnel registered on the payroll of the company or by external service providers. They must conduct a proper risk assessment and repeat this risk assessment regularly.

Depending on the scope of the company's activities, processes, materials and substances being used, physical conditions of the workplace and the outcome of the risk assessment, measures necessary for the protection of employees' health and safety must be taken and these measures must be monitored and updated based on any change in circumstances. Among others, employees must complete health examinations before employment and/or being assigned to a job, before the employee returns to work following repetitive absence from work due to occupational accidents, occupational diseases or health problems, and/or at regular intervals during the term of employment as recommended by the Family, Labour and Social Services Ministry. Employees must receive health and safety training when they are recruited, transferred or change jobs, when there is a change in equipment or new technology is introduced or potential risks change. Each employee working in very hazardous workplaces should prove they received all of the necessary vocational training by presenting the relevant documents to the employer.

All occupational accidents and diseases suffered by the employees are recorded under reports and notified to the Social Security Institution. Similar to the health and safety rules, there is also no piece of legislation specifically regulating the disposal of hazardous waste substances of laboratories. Therefore, provisions from the waste management legislation apply. Under the Regulation on Waste Management , hazardous waste should be collected and disposed separately from other waste and in a secure environment to prevent any leakage. The six-digit waste code, the volume of the waste, the temporary storage date, and a warning regarding hazardous waste should be included on the package of the waste. The storage, including temporary storage, transfer, and disposal of hazardous waste is subject to certain rules and a permit must be obtained from the Environment and Urban Planning Ministry (MoEUP). Among others, enterprises must have their temporary waste storage unit insured under Compulsory Liability Insurance for Dangerous Materials and Hazardous Waste. The enterprise must also prepare a waste management plan to be approved by the provincial directorate of the MoEUP, keep records of all of the waste produced by the enterprise, fill out a waste declaration form electronically before the end of March each year and keep copies of completed forms for five years, train employees on waste management and take all necessary health and safety precautions. If the waste is disposed of in the environment because of an incident, the enterprise should notify the regional directorate of the MoEUP within 24 hours and prepare and submit a report on the details of the incident within 30 days. If a laboratory produces medical waste, then the disposal process relevant to the medical waste is subject to the Regulation on Control of Medical Waste. Under the regulation, it is forbidden to release medical waste both directly and indirectly to the receiving environment and those who are involved in the collection, transportation, temporary storage and disposal of medical waste are jointly liable for any damages arising from environmental pollution and damage caused by medical waste.

Laboratories are listed as healthcare institution under this regulation. Under the regulation, healthcare institutions must establish a system to minimise waste and prepare and implement a medical waste management plan, which will regulate waste management related issues such as the separate collection of medical waste, the transportation of waste in healthcare institutions, temporary storage and the measures to be taken in case of an accident. Different types of wastes (e.g. medical wastes, hazardous wastes, non-hazardous wastes, packaging, municipal waste) should be collected separately and medical waste should be collected and temporarily stored in medical waste bags or containers in different colours depending on the content of the waste and must bear both an International Biohazard logo and a warning regarding medical waste. Waste bags and pathological waste collection containers can never be carried by hand and contact between the waste and body should be avoided. Containers and buckets must be cleaned and disinfected every day.

The details of the medical waste produced are recorded. Institutions fill out waste declaration forms for the medical wastes produced in the previous year, submit them to the MoEUP electronically before the end of March annually and keep a print out of the form in its records for five years.

Municipalities or third party service providers appointed by the municipalities are responsible for collecting, transporting and disposing of medical waste. Therefore, healthcare organisations execute a protocol with the municipality. Institutions may need to temporarily store the medical waste until it is collected.

The personnel in charge of the management of medical waste should be trained on the rules to follow during the collection, transportation, temporary storage, sterilisation and disposal of medical waste, the injuries and diseases the waste may cause and the measures to be taken at the time of an accident or injury. Personnel attending training should also be provided with a certificate and special protective clothing and equipment, must be immunised and must have check-ups at least once every six months.

20. Are there any specific rules governing testing of pharmaceuticals on humans or animals?

Testing of Pharmaceuticals on Humans

The main legislation governing the testing of pharmaceuticals on humans in Turkey is the Regulation on Clinical Trials, which provides in-depth regulatory requirements. There are also Good Clinical Practice Guideline published by the PPMDA, which was drafted based on the World Medical Declaration of Helsinki Ethical Principles for Medical Research 1964.

Under the Regulation on Clinical Trials, clinical trials must first be performed on non-humans in a vitro environment or on a sufficient number of test animals before it can be conducted on humans. Clinical trial sponsors must also obtain authorisation

from the PPMDA, where necessary and approval from a local ethics committee to initiate a clinical trial. If it is decided the potential risks of the clinical trial is greater than its potential benefits, the clinical trial is not approved. The PPDMA also publishes certain details of the approved clinical trials in an online publicly available platform.

Additionally, clinical trial subjects or their legal representatives must be informed about the details of the clinical trial, including the objective of the trial, the methodology to be used, expected benefits, foreseeable risks, difficulties, properties of the trial which may be unfavourable to the subject's health or personal traits, conditions to conduct the trial and subject's right to withdraw from the trial. On informing the trial subject of the above issues in an easily understandable manner, their consent must be collected in a written clinical trial subject informed consent form, the content of which must also approved by the ethics committee. The clinical trial subjects must also be insured for any risks which may be triggered because of clinical trial. Apart from the insurance benefit, the Regulation on Clinical Trials prohibits offering any benefits to the clinical trial subjects which may encourage them to participate in clinical trials. The regulation also provides detailed rules and additional requirements for different categories of trial subjects such as children, pregnant woman, new/nursing mothers, wards and patients in intensive care.

Clinical trials can be conducted in university training and research hospitals, including military training and research hospitals, certified training and research centres and public training and research hospital associations by a qualified research team. The Good Clinical Practice Guidelines provide further details on the requirements for the research centres, the members and the leader of the research teams.

Any changes which occur regarding the conditions, risks, or any of the information provided to the PPMDA and/or the ethics committee at the application phase and any adverse events which take place during the clinical trial are notified to the PPMDA and the ethics committee. Their approval is further required if necessary in line with the Good Clinical Practice Guideline. The research team leader and the sponsor record all the information relating to clinical trials and these records are kept for five years commencing from the completion date of the clinical trials at all research centres involved in the clinical trial. The details of the clinical trial are explained under interim and periodic reports (e.g. annual evaluation report) which are submitted to the PPMDA. On completing a clinical trial at all research centres involved, summary of the completion report and a version of this summary drafted in an easily understandable manner by the subjects are prepared and submitted to the PPMDA.

Failure to comply with the legislation and not obtaining the necessary approval for a clinical trial does not only result in administrative sanctions under the Regulation on Clinical Trials, but may also constitute a criminal offence (i.e., the use of humans for experimental purposes) under Article 90 of the Turkish Criminal Code.

Testing of Pharmaceuticals on Animals

The main legislation governing the testing of pharmaceuticals on animals in Turkey is the Regulation on the Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes (Regulation on Protection of Animals Used for Experiments) and the Regulation on Working Procedures and Principles of the Ethics Committee of Experiments on Animals (Regulation on Ethic Committee of Animal Experiments). Both of these regulations include provisions parallel to the Directive 2010/63/EU of the European Parliament and of the Council on the Protection of Animals Used for Scientific Purposes.

Under the Regulation on Ethic Committee of Animal Experiments, experimental animals can be used for developing, manufacturing and achieving safety tests for medicines, vaccines, food and other substances or products. However, experimental animals will be taken from a legal supplier or produced for experimental purposes in order to be used for that specific purpose. In order to avoid any ethical problems which might arise, the Regulation on Ethic Committee of Animal Experiments sets out the ethical standards regarding the methods and materials used for scientific research, tests and education done on experimental animals. It also provides for the establishment of Central and Local Ethics Committees of Experiments on Animals, which will approve all of the procedures to be followed relating to experimenting on animals. Finally, it sets out the rules and procedures for monitoring, controlling and recording experiments done on animals.

The Regulation on the Protection of Animals Used for Experiments also regulates in-depth rules on the applicability to breeders, suppliers, users and authorised researchers for their institutions, employees and the procedures (as the term being used for actions including experiments in the legislation). Under the regulation, breeders, suppliers, users and authorised researchers must obtain a series of permits from the MoAF to establish and operate their institutions. If an animal experiment will be carried out outside the authorised institution, then a separate and additional permit must be obtained from the MoAF for the procedure.

A veterinarian must be appointed as a responsible manager for each institution and an animal welfare unit must be established. The responsible manager is under an obligation to ensure the practices in the institution are in compliance with the legislation and all precautions are taken to ensure the animal welfare, welfare and good health of the employees working in the institutions and secure storing and disposal of the wastes generated in the institution. The MoAF records the information of the responsible manager and any other veterinarians working in an institution. Therefore, any change to the responsible manager or veterinarians must be notified to the regional directorate of the MoAF. The personnel working in the institution must be trained on animal welfare, animal health and public health.

In addition, breeders, suppliers, users and authorised researchers must keep records of the animals for at least five years and shared with the MoAF on request. They should also fill out the template forms published by the MoAF, which requires information on the animals held in the previous year and submit these forms to the regional directorate of the MoAF untill the end of January each year.

The Regulation requires the users to choose the most appropriate methods. Accordingly, the procedure should not be made on the animals, if there is another method or testing strategy, which does not require the use of a live animal, available for obtaining the result is sought. When choosing between experiments, those using the least number of animals, involving animals with the lowest capacity to experience pain, suffering, distress, or lasting harm and/or cause the least pain, suffering, distress, or lasting harm should be selected. Experiments which may lead to death of the animal should be avoided as much as

possible. Unless it is inappropriate, procedures are carried out under general or local anaesthesia and analgesia or another appropriate method is used to ensure pain, suffering and distress are kept to a minimum. Procedures which involve serious injuries which may cause severe pain will not be carried out without anaesthesia. The procedures are classified as 'non-recovery', 'mild', 'moderate' or 'severe' on a case-by-case basis using the assignment criteria stated under the Regulation on the Protection of Animals Used for Experiments.

When no further observations are to be made for that procedure or, expected to experience pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle, an animal experiment is ended. Following the completion of a procedure, a decision is made by a veterinarian on whether to keep an animal alive Where an animal is to be kept alive, it should receive care and accommodation appropriate to its health. If their health allows, there is no danger to public health, animal health or the environment and appropriate measures have been taken to safeguard the well- being of the animal, then the animals used or intended to be used in procedures may be allowed to be rehomed, or returned to a suitable habitat or husbandry system appropriate to the species.

21. Do rules on dispensing drugs to animals differ from those in dispensing to humans?

Although the authorisation and relevant procedures for medicinal products for human use and veterinary medicinal products are similar in many aspects, there are also differences as they are regulated under different legislation and are under the surveillance of different regulatory authorities. Accordingly, dispensing veterinary medicinal products to animals is also slightly different from dispensing pharmaceutical products to humans.

Law No. 5996 and the Regulation on Veterinary Medicinal Products primarily govern the dispensing of veterinary medicinal products to animals, subject to the licensing and surveillance of the MoAF. Similar to medicinal products for human use, veterinary medicinal products can be manufactured in Turkey or imported to Turkey by institutions who hold licenses issued by the MoFA and which fulfil the requirements listed under this legislation. These products are bought by pharmaceutical warehouses or veterinary pharmaceutical warehouses authorised for the wholesale of veterinary medicinal products under Law No. 5996 and the Regulation on Veterinary Medicinal Products and are then sold and delivered to pharmacies, veterinary clinics, polyclinics and animal hospitals. Law No. 5996 also regulates the retail sale of veterinary medicinal products can be made through authorised pharmacies, veterinary clinics, polyclinics and animal hospitals, who hold a retail sale permit from the MoAF. The process and requirements for sales permit application is explained in detail in the Regulation on Veterinary Medicinal Products. Similar to medicinal products for human use, veterinary medicinal products can be sold with or without prescriptions depending on the medicinal product. According to Law No. 6343 on the Practice of Veterinarians, the Establishment of Unions and the Society of Turkish Veterinaries, only qualified veterinarians are authorised to prescribe veterinary medicinal products to animals.

A product track and trace system has been also introduced for veterinary medicinal produts by the MoAF, which is similar to the ITS of the MoH for medicinal products for human use.

22. Do the rules on practicing as a pharmacist or selling drugs differ in the free zones?

Free trade zones are regulated under Law No. 3218 on Free Trade Zones (Law No. 3218) and the Free Trade Zones Implementation Regulation . Under this legislation, there are no specific provisions relating to practising as a pharmacist or selling pharmaceuticals. (The Free Trade Zones Implementation Regulation only states transferring narcotic and psychotropic substances and the related chemical substances (i.e. controlled chemical substances) to and from free trade zones are subject to the rules of the MoH.) Similarly, Law No. 6197 and the Pharmacy Regulation are also silent on this subject. However, considering only wholesale trade is permitted in free trade zones, running an independent pharmacy which is allowed to sell pharmaceuticals to patients as retail may not be possible.

23. Do the rules on manufacturing pharmaceutical products or pharmaceutical research differ in the free zones?

Similarly Law No. 3218 and the Free Trade Zones Implementation Regulation is silent on manufacturing pharmaceutical products or pharmaceutical researches. However, based on the official letters of the PPMDA, we understand enterprises manufacturing pharmaceuticals can operate in free trade zones subject to the requirements of Law No. 984 and the legislation and rules published by the MoH. Pharmaceutical manufacturers operating in free trade zones are subject to the same rules and requirements of the MoH applicable to pharmaceutical manufacturers outside of free trade zones, but additionally, they are subject to the rules and requirements of enterprises operating in free trade zones under Law No. 3218 and the Free Trade Zones Implementation Regulation. To sum up an operation certificate must be obtained from the General Directorate of Free Trade Zones on the completion of the application process explained under the Free Trade Zones Implementation Regulation. Any changes in the information declared during the operation certificate application (including, among others, shareholding structure, articles of association) must be notified to the regional directorate. Certain registrations must be made for each vehicle and the people entering the free trade zone, including employees, subcontractor employees and even visitors, before the free trade zone administration and entry permits must be issued. It should also be noted transferring a product from a free trade zone to outside is considered an 'import' and transferring a product to a free trade zone from outside is considered an 'export'. Therefore, the import and export related requirements of the customs authority and the MoH apply.

24. How do product safety and personal injury legislation operate in situations where a patient has been injured as a result of drug which was dispensed or manufactured in this jurisdiction?

If a patient is exposed to an adverse reaction or is suspicious which a licensed pharmaceutical product caused an adverse reaction, the patient should notify Turkish Pharmacovigilance Center (TUFAM) by filling an online adverse event notification form, calling the TUFAM call centre during business hours, or by sending the filled in adverse event notification form to the TUFAM by post, e-mail or fax.

The adverse event notification form to be filled out by the patients should contain the following information:

- a) Information on the patient experiencing the adverse event (e.g. initials, age/date or birth, gender, height, weight, medical history, information on pregnancy);

  b) Information on the adverse event (e.g. a description of the adverse event and its occurrence, the date of occurrence, seriousness of the event, current situation of the patient who faced the adverse event, other notable information such as other medicines used to cure the adverse event, etc)

  c) Information on the pharmaceutical product suspected of causing the adverse event (e.g. product name, dosage, for which disease it was used to treat, start and end dates of using the product, details of any other pharmaceutical products being used simultaneously, etc)

  d) Information on the person reporting the adverse event (e.g. name, surname, telephone number, e-mail address, postal address, the name of the doctor and/or the healthcare organisation, permission to contact the doctor relating to the adverse event)

The Regulation on the Safety of Medicinal Products also requires healthcare professionals and marketing authorisation holders to notify any observed adverse effects to the TUFAM within 15 days. The form to be used for the notifications by healthcare professionals and marketing authorisation holders have similar content to the form filed by patients but requires further details on the pharmaceutical product suspected of causing the adverse event, the use of the product, the occurrence and duration of the adverse event, the tests made and the treatment received by the patient relating to adverse event and information on the license holder.

On receiving adverse event notifications through the TUFAM, the PPMDA evaluates the applications and the potential risks. Accordingly, the PPMDA may rule to

- (i) conduct a post-authorisation study,

  (ii) implement risk minimisation measures,

  (iii) suspend or revoke existing licenses or reject requests for extending the validity period of the marketing authorisation,

  (iv) prohibit procurement of the medicinal product, or

  (v) change the product information (such as decreasing the recommended dose, adding new contraindications, limiting the scope of indications, etc), whichever it considers necessary depending on the case.

A patient injured because of a pharmaceutical product can seek compensation from the manufacturer of the product before a civil court under the Code of Obligations and the Law No. 6502 on the Protection of Consumers .According to Article 49 of the Code of Obligations, a person who caused damage to another through a fault-based or unlawful act must pay compensation for this damage by proving the unlawful act, the fault of the perpetrator, the damage they suffered and a causal link between the act and the damage.

Law No. 7223 on Product Safety and Technical Regulations (Law No. 7223), which was recently adopted, will enter into force on 12 March 2021. Law No. 7223 regulates the rules applicable to all marketed products. If a product causes harm to someone, the manufacturer or importer of the product which is the marketing authorisation holder in this case is responsible for remedying the damage, subject to the condition the person who suffered the damage proves the causal link between their damage and the defect of the product (similar to the requirements under the Turkish Code of Obligations for tort claims). Law No. 7223 also states if there is more than one manufacturer or importer responsible for the damages, then they will be severally liable and refers to the Code of Obligations provisions for the determination and calculation of material and immaterial damages.

Although the manufacturer and market authorisation holder who produce or import a defective pharmaceutical product is liable for damages under the product liability legislation, in practice, it is commonly seen patients sue physicians for complications caused by defective medicinal products through malpractice lawsuits and claim compensation.

According to the Regulation on Patient Rights, patients are also entitled to claim reimbursement for both material and immaterial damage from the healthcare organisation employing the person infringing the rights of a patient. However, if the healthcare organisation is a public organisation, the claim must be resolved before an administrative court.

Unlike the practices in several foreign jurisdictions, class action lawsuits are not an option under Turkish law. Therefore, there are no class action claims against manufacturers or market authorisation holders for defected pharmaceutical products. However, under Article 113 of the Civil Procedure Code, associations and other legal entities can bring lawsuits to protect their members' interests. Therefore, it is possible for consumer associations to file lawsuits on behalf of their members for product liability claims.

25. Are there any drugs or therapies which are barred or have restrictions on their dispensing because of religious reasons?

No.

Firm

Hergüner Bilgen Özeke*https://herguner.av.tr/*

Description

Since 1989, we have strived to reshape the Turkish law firm model in harmony with modern standards of professional practice while still preserving the personal attention that our clients have come to expect. Our pioneering efforts have allowed our firm to be rightfully recognized as the first "Full Service Law Firm" in Turkey.

Full service independent law firm

Throughout our history, we have chosen to remain independent of global coalitions. This has given us the flexibility to adopt the best global practices and apply them to the necessities arising in local practice. We independently built the foundation for the modern Turkish legal practice models and are proud of where our determination has taken us. Nonetheless, we recognize that client's needs evolve and our innovation continues to improve the services that can be offered. We have never rested on our laurels, and we will continue to work just as hard to remain ahead of the curve.

Our size and expertise make us one of the few truly full-service independent Turkish law firms with a global reach, either at home in the role of primary counsel or as local counsel for our foreign and domestic clients. Our firm's expertise and institutional knowledge enables us to go beyond simple lawyering and develop creative business-oriented solutions according to client needs. We accomplish this by putting clients first and becoming intimately acquainted with all aspects of their business and legal needs.

A large team with unprecedented experience

We take full advantage of our size: every project is handled by a unique project team composed of attorneys with the precise area of expertise and level of experience that the task requires. Our project teams are led by an exceptional corps of partners, each with decades of experience managing landmark projects in every practice area. Each new project calls for a different team composition which allows our attorneys to absorb more institutional knowledge and create ever-increasing synergies throughout project lifecycles and across practice areas. Our experience in international transactions allows us to assist clients expanding into other markets by collaborating closely with local counsel in developing economies throughout the MENA region.

Known for innovation

The firm's reputation for innovation goes back almost three decades, having drafted many first-of-its-kind agreements in cross-border transactions that continue to be used as model agreements in the market today. Our output continues to set industry standards, as our attorneys combine their experience in global transactions and international education with their strong base in Turkish law to generate unique client solutions.

Understanding your business

In today's rapidly changing business environment, decision makers need two things to be successful: trust in relationships and insightful advice at work. Understanding and meeting the expectations of business leaders requires rethinking how legal advice should be provided. We believe our expertise is meaningful to the extent that it helps you achieve your business objectives. This is why our ambition is to go beyond delivering technical answers to legal inquiries. We strive to understand your business in its entirety and provide solutions for your success.

Authors

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Education

Kayra received his LLB from Marmara University in 1998 and his LLM. from Georgetown University Law Centre in 2000.

Biography

Kayra Uçer specialises in M&A, Corporate Support, Competition, and Employment law with ample experience across a number of sectors including the heavily regulated medical devices and pharmaceuticals industries. He has significant experience representing different names in the pharmaceutical industry with respect to all of their legal needs including handling all of the corporations' daily corporate work, employment issues, and regulatory needs. Kayra also known for his outstanding contributions to the development of corporate governance through his long-standing involvement with the Corporate Governance Association of Turkey.

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Education

Melike received her LL.B. from Yeditepe University in 2010. During her LL.B. studies, she studied at the Erasmus University of Rotterdam as exchange student and participated in a summer program on contract and tort law at American University Washington College of Law.

Biography

Melike Gençalp focuses her practice in Data Privacy, Corporate Support and Employment law with ample experience across a number of sectors including the heavily regulated pharmaceuticals industry. She has experience representing different names in the pharmaceutical industry with respect to all of their legal needs including handling all of the corporations' daily corporate work, employment issues, contract issues and regulatory needs.

She has published a number of articles on a variety of topics in corporate law and data protection law in various sectors. She also contributed to the articles on pharmaceutical law and participated as panelist in several industry specific panels.