



INTERNATIONAL ASSOCIATION OF YOUNG LAWYERS

**Distribution of Pharmaceuticals and Medical Devices
How Arnold Schwarzenegger became Terminator**

**Commission in charge of the Session:
Distribution Commission**

London, 2015

Moritz Maurer, LL.M.

Attorney at Law

Pestalozzi Attorneys at Law Ltd

Löwenstrasse 1

CH-8001 Zurich

Switzerland

19. May 2015

Introduction

The distribution of pharmaceuticals and medical devices (the "Distribution") as well as the underlying agreements between suppliers and distributors (the "Distribution Agreements"), are subject to a strict regulatory regime. Manufacturers/suppliers have to observe comprehensive security and other provisions whenever medical devices/products are put on the market.

This questionnaire shall therefore address the following topics with respect to jurisdictions of France, Switzerland, Germany and Argentina: latest novelties and/or developments, legal framework, building blocks, form and formalities, important provisions, continued supply, specific provisions, incoterms, clientele compensation, product liability and intellectual property.

General Report

Latest Novelties and/or Developments

The following describes the latest novelties and/or developments with respect to the Distribution.

a. France

In order to allow the sale of medicinal products on the internet, France transposed EU directive no. 2011/62 of 8 June 2011 (which aims to combat the falsification of medicinal products) via ministerial order no. 2012-1427 of 19 December 2012 and decree no. 2012-1562 of 31 December 2012. Furthermore, a ministerial order of 20 June 2013 set out a list of good practices for the e-distribution of medicinal products.

The ministerial order no. 2012-1427 of 19 December 2012 having been successfully challenged before the Conseil d'État (France's highest administrative court), article L5125-34 of the French Public Health Code, which stated that only non-prescription medicines included in the list of medicines available in pharmacies ("liste de médication officinale") could be sold online, was rescinded (Conseil d'État, 17 July 2013, nos. 365317, 366195, 366272, 366468). Therefore, all medicinal products except prescription-only medicines may be sold online, whether they are included in the list or not.

Decree no. 2012-1562 of 31 December 2012 was also challenged before the Conseil d'État, albeit unsuccessfully (Conseil d'État, 16 March 2015, no. 366531).

Finally, the ministerial order of 20 June 2013 was also challenged before and rescinded by the Conseil d'État (Conseil d'État, 16 March 2015, nos. 370072, 370721, 370820) because it exceeded the scope of the powers devolved to the Minister by law. From a procedural standpoint, the Conseil d'État found that the order included "technical rules" that, pursuant to a directive of 22 June 1998, should have been notified beforehand to the European Commission.

b. Switzerland

Changes to the Swiss Federal Therapeutic Products Act are underway in order to improve (1) public access to pharmaceuticals and (2) the conditions for biomedical research and manufacturing. The aim is to facilitate market access for complementary

and herbal medicines/pharmaceuticals and increase the availability of a broader range of pharmaceuticals that are suitable for children.

Further, in particular with respect to the Distribution, there are also amendments to regulations on discounts and incentives of monetary value, which are offered by manufacturers to physicians and pharmacies in order to promote their products.

The following objectives are pursued with the revision of the Therapeutic Products Act:

- simplification of market access;
- improvement of the safety of medical products;
- increasing the transparency of information on medical products;
- clarification of controversial legislation and regulations and removal of legislative loopholes; and
- examination of the institutional framework.

The following areas are concerned by the upcoming revision:

- medicinal products for pediatric use;
- synthetic, complementary and herbal medical products;
- supply of medicinal products;
- information on medicinal products;
- improvement of market surveillance;
- handling medicinal products (therapeutic safety);
- import of medicinal products; and
- benefits of monetary value.

The revised Act is scheduled to enter into force in the year 2017

c. Germany

One of the most significant developments in respect to the Distribution is art. 5 (1) lit. b of the new Commission Regulation (EU) No. 316/2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements. According to art. 5 (1) lit. b of the Technology Transfer Block Exemption Regulation so called “termination clauses” do not benefit from the exemption except in the case of an exclusive licence. A “termination clause” is a clause by which the licensor reserves the right to terminate the licence agreement in case the licensee attacks the licensed right. Henceforth, the admissibility of the international practice of using “termination clauses” will be subject to case-by-case scrutiny by the Commission.

d. Argentina

The most important novelty is the recent (2014) promulgation of the new Civil and Commercial Code (Law No 26.994). For the first time in Argentina, distribution agreements are mentioned in a Code. Article 1511 establishes that the rules of Chapter 18 (Concession Contracts) shall be applied to Distribution Agreements when applicable. The new Code will be enforceable since 1 August 2015.

Legal Framework

The following describes the legal framework applicable to the Distribution, i.e., the applicable national rules and regulations.

a. France

1. Operators

At production level

The first link in the supply chain is of course where drugs are designed and manufactured, but also put into circulation. Only pharmaceutical establishments authorised by the ANSM (the French drug safety agency) may take part in the production process (articles L5124-1 and R5124-2 of the French Public Health Code).

Pharmaceutical companies (*laboratoires pharmaceutiques*)

At the top of the chain are the pharmaceutical companies who design medicines. Most of the time, they also hold the marketing authorisation (the "MA") and manufacture the drug. As manufacturers, they are authorised to perform the following operations: purchasing of raw and packaging materials, production, quality control, batch release, storing (article R5124-2 1° of the French Public Health Code).

Pharmaceutical traders (*exploitants*)

Where the holder of an MA for a medicine does not trade their drugs themselves, they can charge a pharmaceutical trader with storing and wholesaling their drugs to distributors or community pharmacies (article R5124-2 3° of the French Public Health Code).

At wholesale distribution level

Drugs at the wholesale level may be distributed by three types of regulated operators, here, too, must all be pharmaceutical establishments in accordance with articles L5124-1 and R5124-2 of the French Public Health Code.

Wholesale dealers (*grossistes-répartiteurs*)

Wholesale dealers purchase and store medicines (the drugs that community pharmacies cannot make themselves) which they then wholesale unchanged (article R5124-2 5° of the French Public Health Code). Although they usually act independently, they may also purchase and store drugs by order and on behalf of community pharmacies or groupings of community pharmacies, albeit only drugs that are not reimbursed by the social security (article R5124-2 5° of the French Public Health Code).

Wholesale dealers have a duty to deliver pharmacies' orders within 24 hours.

Bailees (*dépositaires*)

Bailees store and wholesale drugs unchanged on behalf of pharmaceutical companies (article R5124-2 4° of the French Public Health Code). They do not own the medicines in their custody.

Pharmaceutical group purchasing organisations (*centrales d'achat pharmaceutiques*)

Pharmaceutical GPOs are a recent addition to the list of pharmaceutical establishments. According to article R5124-2 15° of the French Public Health Code, they purchase and store drugs that are not reimbursed by the social security which they then wholesale unchanged to community pharmacies, either in their own name and on their own behalf or by order and on behalf of community pharmacies or groupings of community pharmacies.

At retail level

According to article R5124-42 of the French Public Health Code, none of the operators mentioned above are authorised to deliver medicines to the public: that is the remit of community pharmacies.

Community pharmacies (*officines pharmaceutiques*)

With a very few exceptions, only community pharmacies are authorised to retail drugs to the public (articles L4211-1 and L5125-1 of the French Public Health Code).

Groupings of community pharmacies (*groupements d'officines*)

Groupings of community pharmacies (mainly trading companies or economic interest groupings) arose from practice and are therefore not governed by the French Public Health Code, although they are described in its article D5125-24-1. They were created by community pharmacies chiefly to increase their bargaining power vis-à-vis suppliers in order to negotiate better terms than members could secure individually, although they also offer members additional services relating to their activity, such as marketing, advertising, statistics and strategic advice.

2. The various types of drug distribution agreements

Agreements between pharmaceutical companies and wholesale dealers

Pharmaceutical companies and wholesale dealers can enter into framework agreements in order to lay down the terms of their contractual relationships.

Agreements between pharmaceutical companies and bailees

Pharmaceutical companies and bailees can also set up their relationships through framework agreements. Since bailees may not own the drugs which

they sell on the pharmaceutical companies' behalf (article R5124-2 4° of the French Public Health Code), they may not on any account purchase the medicines entrusted to them for the purpose of reselling them. When bailees do sell medicines to community pharmacies or wholesale dealers, they are generally acting as commission agents, i.e., in their own name but on behalf of the pharmaceutical company, their principal.

Agreements between pharmaceutical companies and groupings of community pharmacies

Listing agreements

Under a listing agreement, a pharmaceutical company undertakes to sell medicines to member pharmacies throughout the term of the contract at the rates negotiated by the grouping. However, members remain free to buy or not to buy the pharmaceutical company's listed products, for which they contract with the company directly. For its part, the grouping undertakes to advertise the pharmaceutical company's offerings to its members under terms generally set out in the listing agreement (form, periodicity, etc.).

General purchase agreements

Here the grouping of community pharmacies acts as a commission agent, i.e., in its own name but on behalf of the pharmacies, its principals. As with listing agreements, the grouping has to negotiate terms with pharmaceutical companies. Of course, terms will be all the more attractive as the quantities ordered increase.

3. Regulatory framework

Drug prices

On the subject of price, French law differentiates between medicines that are reimbursed by the social security and medicines that are not. Operators may freely set the price for the latter, whereas the price of medicines that are reimbursed by the social security is subject to a threefold cap:

- a maximum selling price for the public;
- a maximum margin for middlemen; and
- a discounts cap.

Prohibition of benefits in kind or cash for community pharmacists

Pursuant to article L4221-17 of the French Public Health Code, it is forbidden for the other operators to grant community pharmacists (and any other health professionals) any benefits in kind or in cash unless in performance of certain specific agreements (for research or scientific assessment purposes) subject to prior notification to the professional associations of health professionals.

However, article L4113-6 of the French Public Health Code mentions that an “agreement” (i.e., prior notification) is not required for either the financing of training sessions or “normal work relationships” although what “normal work relationships” are remains undefined.

Limits to business co-operation services for medicines reimbursed by the social security

Although legal authors are divided on the issue, it would appear that community pharmacists may not perform most of the so-called “business co-operation services” that are common in other, unregulated branches of the economy. The argument is that, as medicines that are reimbursed by the social security may not be advertised to the public (article L5122-6 of the French Public Health Code) and community pharmacists are bound by doctors' prescriptions anyway (with the exception of the right of substitution with generic drugs) most services usually offered by community pharmacies with respect to in-shop advertising and promotion (posters and window-dressing especially) are precluded from the outset.

b. Switzerland

Distribution agreements are generally based on the Swiss Code of Obligations ("CO"), but are affected by the regulatory framework, which mainly consists of the following statutory provisions:

- Therapeutic Products Act (TPA/HMG; SR 812.21);
- Ordinance on Medical Devices (MepV; SR 812.213);
- Act on Human Research (HFG; SR 810.30);
- Ordinance on Clinical Trials (KlinV; SR 810.305);
- Act on Transplants (SR 810.21); and
- Act on Narcotics and Psychotropic Substances (BetmG; SR 812.121).

The Federal Act on Medical Products and Medical Devices (Therapeutic Products Act, TPA/HMG) sets the framework for placing medical products and medical devices on the market. It requires a comprehensive implementation legislation, which is regulated by ordinances.

Apart from domestic provisions, this framework ensures the implementation of requirements of the European directives for medical devices into Swiss substantive law. Monitoring and correct execution of provisions of the therapeutic product regulation is ensured by the Swiss Agency for Therapeutic Products, Swissmedic, and by the Cantonal Authorities in specific areas.

Switzerland has concluded treaties with EU Member States, EFTA States and Turkey with regard to the mutual recognition of conformity assessments for medical devices (bilateral agreements or mutual recognition agreements). The basis for these treaties consists in applying the European guidelines on medical devices and the European CE mark. The contracting states recognize the certificates issued by the Swiss Conformity Assessment Bodies, and in return, Switzerland recognizes conformity assessments carried out by Notified Bodies/Conformity Assessment Bodies in the states in question.

These treaties simplify the mandatory reporting duties for placing devices on the market, and permit direct distribution from Switzerland to all EU/EFTA member states and Turkey, without an authorized representative with registered offices in the said countries. In return, companies with registered offices in the countries concerned can distribute compliant medical devices directly to Switzerland. Notwithstanding the above, country-specific requirements relating to medical devices remain applicable (e.g. notifications for new products, language requirements regarding the product information, provisions regarding prescription and professional use, distribution channels, sales outlets, advertising, reimbursement by social insurances).

c. Germany

The legal framework for the Distribution can be divided into two categories: the general rules applicable to distribution contracts, on the one hand, and the specific rules and regulations which determine the admission, distribution and control of pharmaceuticals and medical devices, on the other hand.

General rules on Distribution contracts can be found in the provisions on sales in the German Civil Code (*Bürgerliches Gesetzbuch*) and in the provisions on commercial agents in the German Commercial Code (*Handelsgesetzbuch*) which can be applied analogously to distributors under certain conditions. Further rules applicable to Distribution can be found in the national and European regulations on competition law, particularly on vertical restraints in distribution and technology transfer contracts.

Moreover, there are special rules which govern the admission, distribution and control of pharmaceuticals in Germany such as the German Pharmaceuticals Act (*Arzneimittelgesetz*) which stipulates the admission, production and distribution of pharmaceuticals and the German Pharmacy Act (*Apothekengesetz*) which regulates the distribution of pharmaceuticals to end users. Furthermore, the sale of prescription-only medicine is governed by the provisions of the German Social Code, Book V (*Sozialgesetzbuch V*).

Special rules on the requirements of the marketing of medical devices in Germany are provided by the German Medical Products Act (*Medizinproduktegesetz*).

Further regulations on the distribution of pharmaceuticals and medical devices can be found in European directives and regulations, such as the Regulation No. 726/2004 on the authorisation and supervision of medicinal products.

d. Argentina

Civil and Commercial Codes do not contain specific provisions for distribution contracts. Rather, a distribution contract is considered a so-called “innominate contract”, which combines, among other things, elements of purchase and sales contracts, commercial agency and mandate agreements. Therefore, if the distribution agreement does not regulate a specific issue, the parties should be enforce by analogy to the statutory provisions related to these three types of contracts as default rules to the extent suitable in a given case.

The most relevant rules regarding the Distribution are the following:

- Law No 16,463 (August 4, 1964) regulates import, export, production, commercialization and deposit of medicines, within national or international jurisdiction (Decree No 9763/64 regulates Law No 16,463);
- Decree No 1299/97: critical stages of medicines commercialization chain;
- Order 7439/99 establishes the conditions to authorize a medical distributor;
- Order 105/2002 ANMAT (National Administration of Medicines, Food and Medical Technology): Distributors registry and control system;
- Order 3475/2005 ANMAT / Decision Mercosur GMC N° 49/2002: “Mercosur Technical rules for Best Practice of Pharmaceutical products distribution”; and
- Order 3683/2011 ANMAT: Medicines Traceability System.

Building Blocks

The following describes the building blocks of Distribution Agreements.

a. France

Distribution agreements generally include clauses setting out the terms and conditions of the whole drug sale process from supplier to distributor, including:

- a definition of the contractual products and of the territory;
- the scope of the rights granted to the distributor (exclusivity or no exclusivity, etc.);
- the terms of sale (order processing, prices, delivery terms, payment methods, etc.);
- the supplier’s obligations such as training of the distributor’s employees, supply of promotional material, etc.;
- the distributor’s obligations such as minimum purchase quantities, minimum promotional budget, warehousing, reporting, etc.;
- warranty and after-sales service;
- IP, if applicable;
- the term, termination, and consequences of termination; and
- the applicable law and jurisdiction.

b. Switzerland

In general, the provisions of a Distribution Agreement are the following:

- parties/whereas: description of the parties’ legal form and area of business, focus and intent;
- definitions: description of the agreement’s most important terms, such as “Product(s)”, “Prices” and “Territory”;
- object of the contract: appointment of the distributor to act as distributor of the product(s) agreed upon in a certain territory;
- obligations/duties of the principal/supplier: mainly supply of product(s), support of the distributor to promote the product;
- obligations/duties of the distributor/customer: purchase of products, protection of supplier’s interests, promotion, reporting regarding sales
- intellectual property: protection of existing trademarks, patents, etc.;

- default/product liability;
- duration of the agreement and termination/consequences of termination: in particular terms of termination prior to end of the agreed term, compensation, non-compete clauses; and
- governing law/jurisdiction.

c. Germany

A typical Distribution Agreements may be structured as follows:

- Appointment of distributor (definition and scope of distribution, e.g., exclusivity)
- Subject-matter of contract (description of the (category of) products that are subject to distribution)
- Contractual area (definition of the sales area)
- Rights and duties of distributor (right and duty to market and promote sales, definition of sales channels, duty to develop promotional activities, duty to report)
- Compliance with laws and regulations (duty and responsibility of distributor to comply with laws and regulations applicable to the Distribution in the destination country/region)
- Regulatory issues and product recalls (definition of responsibilities for regulatory issues (e.g., admission of pharmaceuticals), definition of duties in case of product recalls)
- Sales targets (specification of sales targets, consequences of non-compliance with sales targets (e.g., termination of exclusivity and/or contract))
- Rights and duties of the supplier (duty to supply contractual products to distributor, terms and conditions of consignment, payment, transfer of title (often stipulated in separate annex to contract), duty to advise and provide necessary information/documentation on contractual products)
- Intellectual property (subject matter and scope of distributor's right (licence) to use the trademarks of the supplier in the course of its sales activities)
- Term and termination of contract (duration of contract and conditions of premature termination)
- Effects of termination (cessation to use trademarks, conditions of sale of remaining stocks)
- Indemnification and liabilities (limitation of liability of the supplier, distributor's duty to indemnify and hold harmless the supplier against claims of third parties)
- Non-compete clause
- Confidentiality clause
- General provisions

d. Argentina

In general, the provisions of a Distribution Agreement are the following:

- legal identity of the parties;
- appointment of distributor (specify whether it's exclusive or non-exclusive; set forth territory; and permit or prohibit appointment of sub-distributors);
- term;

- define products and reservation of rights;
- pricing terms (e.g. initial, notice for changes);
- terms of payment (e.g. currency, letter of credit).
- performance requirements (e.g. sales targets, remedial measures, forecast);
- procedures related to ordering and shipping (e.g. risk allocation, traceability);
- supplier's responsibilities (e.g. min. & max. order, technology support, marketing, recall);
- distributor's responsibilities (e.g. inventory, reporting, training, cold chain, recall, good practices);
- government filings or approval (allocation of responsibility, registration of distributor);
- warranty (defective product procedure, returns);
- intellectual property rights (e.g. parties' rights, granted and reserved);
- termination (e.g. renewal, special circumstances);
- non-circumvention & confidentiality;
- assignment;
- post-termination rights;
- dispute resolution process;
- non-compete provisions.

Form and Formalities

The following describes the form and formalities requirements for Distribution Agreements.

a. France

In order to be valid, all pharmaceutical distribution agreements must be made in writing.

Such writing can take the form of either a master agreement followed by implementing agreements or a so-called “consolidated agreement” (“convention unique”, article L441-7 of the French Commercial Code).

Consolidated agreements lay down the special terms and conditions and list the services to be performed both upon the resale of the products and to promote the business relationship between supplier and middleman. A consolidated agreement is required and must be signed before 1 March of the current year if the terms negotiated by the parties go beyond or depart from the pharmaceutical company's rates and/or general terms and conditions of sale. This is the case, for instance, if the parties agree on special terms and conditions.

In principle, consolidated agreements are not subject to disclosure to third parties. In fact, contrary to the general terms and conditions of sale which suppliers have a duty to disclose pursuant to article L441-6 of the French Commercial Code, consolidated agreements are deemed to be a business secret.

Any agreement providing for services to be performed by a community pharmacy, a grouping of community pharmacies, or a wholesale dealer (formerly known as “busi-

ness co-operation services” or “separate services”) must also set out the purpose, planned date, and terms of performance for each service as well as the products or services concerned.

If a listing agreement has been entered into by a pharmaceutical company and a grouping of community pharmacies acting as its members' agent, the former must enter into a written contract with every one of the latter's members

Failure to comply with the form requirements of article L441-7 of the French Commercial Code carries a criminal penalty in the form of a fine (75,000 euros for natural persons and 375,000 euros for legal persons).

In addition, good distribution practice (GDP) in France requires referencing all documentation relating to the business relationship in a written document, including all instructions from the pharmaceutical company or trader to the wholesale dealers or bailees as well as all procedures relating to the delivery, control, storage, etc. of pharmaceuticals and medical devices, which can then be appended to the distribution agreement.

b. Switzerland

Distribution Agreements do not require a specific form. However, the regulatory framework with regard to pharmaceuticals and medical devices regularly burdens the parties with numerous formal obligations, in particular with respect to product safety, clearance and surveillance.

c. Germany

Distribution Agreements generally do not require a particular form. However, for the purposes of clarity and proof it is highly recommended to conclude a written contract.

d. Argentina

Distribution Agreements do not require a specific form.

Important Provisions

The following describes the important provisions from a supplier's perspective and a distributor's perspective.

a. France

From the supplier's perspective, clauses that define the scope of the distributor's duties precisely are highly important because they ensure a smooth relationship. It is for instance very important to define whether the distributor is to be granted exclusivity or not. If so, it is crucial to include in the agreement a mechanism allowing the supplier to monitor the quality of the distributor's work, such as quotas or objectives. The purpose of such clauses is generally to give the supplier a chance to terminate the contract if the distributor should fail to perform their duties properly so that the supplier can safeguard its business and image on the contractual territory.

From the distributor's perspective, provisions such as warranties, after-sales services, and respective liabilities are important because they set out who bears what risks,

thereby enabling the parties to foresee and monitor the distributor's liability in case, e.g., of a defective contractual product.

b. Switzerland

From the supplier's perspective, the following provisions are of particular interest:

- guaranteed quantity of sales in the agreed territory;
- broad right to conduct price adjustments;
- right to vary the product(s): this is particularly important with a view to possible recalls and developments of the product;
- right to maintain IP-rights;
- protection and promotion obligations of the distributor;
- distributor's obligation to abstain from purchasing/supplying competitive products; and
- shifting of regulatory obligations with regard to products to the distributor (to the extent possible).

From the distributor's perspective, the following provisions are of particular interest:

- exclusivity with regard to a certain territory;
- sales support by the supplier;
- indemnification in cases of product liability (in particular in cases of recalls/market withdrawals);
- transfer of risk: this may be of particular importance in case of a highly sensitive product (such provision may be equally important to the supplier);
- extensive complaint period with regard to defective products;
- soft competition clause (if any); and
- customer protection.

c. Germany

One provision which is at the heart of a Distribution Agreement from the supplier's perspective is the duty to promote sales. It is in the vital interest of the supplier to establish a strict regime on the sales activities of the distributor which also provides for clear remedies in case distributor fails to meet sales targets. Another important element of the Distribution Agreement in the perspective of the supplier is the protection of its intellectual property from undue exploitation by the distributor. The supplier may also have an interest to avoid paying an indemnity for clientele to the distributor at the end of cooperation.

From the distributor's perspective a strong regime on the uninterrupted supply of the contractual goods is essential. Furthermore, if the distributor's business requires significant investment, he may want to ensure that the duration of contract is sufficient so as to ensure that his investments can be compensated during the term of the contract. In respect to the clientele established during the contract term, of course the distributor has an interest to ensure to receive an indemnification upon termination of contract.

d. Argentina

From both the supplier's and distributor's perspective, the following provisions are of particular interest:

- force majeure (considering that Argentina tends to be an unstable environment for business due to political reasons, parties may be interested in considering the possibility of including acts of law/change in law and government acts within the scope of force majeure of the agreements) and
- insurance of products.

From the supplier's perspective, the following provisions are of particular interest:

- payment (if international, without taxes, provisions to receive full amount with no deduction or withholding);
- currency (due to unstable of Argentine Pesos, its important to establish it and price increase if necessary);
- product recall;
- lead time;
- delays; and
- stock conditions.

From the distributor's perspective, the following provisions are of particular interest:

- returns;
- product registration;
- defective product;
- product samples;
- clientele compensation.

Continued Supply

The following describes how a customer can ensure continuance of supply (e.g., in case of production interruption) to the extent particular goods are of strategic importance for him.

a. France

The duties of wholesale dealers

Wholesale dealers must have a stock of drugs including at least nine tenths of all medicines (in their various forms) effectively marketed in France in order to effectively cover the needs of the registered wholesale territory.

Wholesale dealers have the following public service duties:

- to cover at all times the consumption of their usual customer base on a biweekly basis;
- to deliver any order placed before 2 pm on a Saturday within 24 hours; and
- to take turns to be on call during weekends and public holidays.

Emergency call centers

In accordance with the French act no. 2011-2012 of 29 December 2011, decree no. 2012-1096 of 28 September 2012 provided for emergency call centers to be set up by pharmaceutical companies that trade their medicines themselves in order for community pharmacies and wholesale dealers to notify stock shortages. These call centers are organised in such a way as to take care at any time of any disruption in drug supplies and to ensure the effective dispensation of the medicine affected by the shortfall, either in advance or after the fact depending on when the shortfall is confirmed by wholesale dealers or bailees. Pharmaceutical traders inform the ARS (French regional health agency) with jurisdiction over the pharmacist concerned of any emergency buying on a quarterly basis, stating the name of each consignee and the quantities supplied (article R5124-49-1 of the French Public Health Code).

b. Switzerland

It is not unusual that a customer reserves the right to terminate the Distribution Agreement at short notice in the event of non-performance, including the cases of interruption in production, e.g. as follows (simplified):

“The distributor shall have the right to terminate the agreement forthwith by written notice in the event of any breach, non-observance or non-performance by the supplier or if the supplier becomes unable (for whatever reason) to ensure timely delivery of the product.”

In order to be effective, the customer’s right must be combined with according exemptions from possible loyalty and non-compete clauses in this particular case.

c. Germany

Different measures can be taken in order to ensure continued supply with goods of strategic importance for the distributor. One option is to insert a clause with strict remedies in case of non-performance. Such remedies may include the permission to purchase the products from a competitor. Other remedies may include provision on liquidated damages in case of non-performance.

d. Argentina

Customers shall have sufficient supply arrangements in place to ensure that medicines are distributed in an efficient and timely way in order to meet patients' needs. In planning stock holdings, customers should hold a reasonable volume of stock to ensure continuity where there are fluctuations in demand. For example, if there is a sudden reduction in parallel import availability or where there are time lags or reliability issues with the data used to forecast demand.

Specific Provisions

The following describes how Distribution Agreements differ from other types of agreements.

a. France

Under a Distribution Agreement, a distributor is granted by a supplier the exclusive or non-exclusive right to sell and promote the latter's products on a defined territory. From a practical standpoint, the distributor purchases products from the supplier and resells them for a profit to customers located within the contractual territory.

A distribution agreement is neither a sales nor a purchase contract. It is a specific framework agreement that establishes the rules governing the global and recurrent relationship between a supplier and its distributor and ensures the quality of the relationship. Not only do distribution agreements govern the sale/purchase operations themselves, they generally also include provisions regarding, e.g., the products' promotion within the contractual territory.

Distribution Agreements differ from other types of agreements such as:

- agency agreements: under an agency agreement, the agent acts as a simple middleman between supplier and customer. Therefore, agents never own the products sold to them by their suppliers. Agents enter into sales contracts with customers in the name and on behalf of the supplier and they earn a contractual commission on each sale. Therefore, sales are concluded directly between supplier and customer, with the agent having only a certain power to negotiate the specific terms and conditions of the sales contract; and
- promotion agreements: Under a promotion agreement, the service provider does not sell or purchase products, they are in charge of communicating about the products and organising advertising campaigns within a specific territory.

b. Switzerland

As a result of the regulatory environment, Distribution Agreements differ from other agreements in accordance with the CO for several reasons:

Sale and use of medical devices

A distributor, who imports medical devices into Switzerland and delivers them to trade intermediaries, points of dispensation or end customers is the so-called initial circulator/distributor in the market. The person providing or transferring a product or device in Switzerland for the first time is considered an initial circulator. Secondary circulators/distributors are market players who distribute or dispense products (e.g. to the end customer) which had previously been brought to the Swiss market by an initial circulator.

Distributors/circulators must observe the following:

- precautionary measures defined by the manufacturer for the storage and delivery of its medical devices;
- ensure that the following restrictions are observed: certain products are subject to prescription (e.g. medical devices which contain a pharmaceutical subject to pre-

scription, certain compressed devices for appetite reduction); in vitro diagnostic devices for the diagnosis of transmissible diseases may not be issued to the general public;

- certain operational requirements might have to be met;
- ensure availability of professional consultation for customers;
- participate in product surveillance, forward information regarding problems with medical devices to those responsible for initially putting the product on the market and implementation of corrective measures.

Further, the Swiss legislation on Therapeutic Products describes the duties of professional users of medical devices (e.g. physicians, nurses, therapists). They must notify incidents and severe health hazards regarding medical devices to the Swiss Agency for Therapeutic Products (Swissmedic), ensure the proper refurbishment and maintenance of medical devices and comply with provisions applicable for the use of certain product groups.

When ensuring that due diligence obligations towards patients are adequately met, the correct application of the manufacturer's instructions can be crucial. In the event of deviations, possible consequences should be clarified and a risk analysis must be prepared.

Points of dispensation as well as facilities where medical devices are applied on patients may need authorisations from the competent Cantonal authorities. Information on operating and professional licenses can be obtained from the respective Canton. Information on the disposal of medical waste can be obtained from the Federal Office for the Environment (FOEN).

Product surveillance

All distributors/circulators of medical devices, in particular the afore-mentioned (e.g. manufacturers, importers, wholesalers, retailers), are obliged to participate in so-called product surveillance and maintain a functioning product observation system (Post Market Surveillance; PMS). PMS includes the collection of information on the properties/characteristics of pharmaceuticals and medical devices during their use (safety, quality, durability, performance), evaluation of the data, the implementation of required improvement measures and, if necessary, the planning and implementation of safety measures in the market.

Tasks of the initial distributor (e.g. manufacturer, importer)

The initial distributor is obliged to maintain a functioning PMS system designed to ensure that all relevant PMS information is collected and evaluated, the technical documentation (incl. clinical evaluation report) is periodically updated with data from product surveillance, investigations and corrective actions are initiated and, if necessary, safety measures are implemented in the market (e.g. withdrawal of products, technical updates, warnings to customers). The initial distributor must report any incidents in Switzerland and respective safety measures to Swissmedic (Materiovigilance and Field Safety Corrective Actions, FSCA). The Materiovigilance System is designed to prevent reoccurrence of serious incidents. The initial distributor is responsible for investigating

the causes of any event and for implementing necessary safety measures. These procedures are monitored by Swissmedic. If problems occur with medical devices, it is important for the company concerned to be able to translate the information received into safety measures and to dispose of an effective system for the withdrawal of products or any other safety measures, including the traceability of its medical devices in the market. Depending on the risk potential in the individual case, traceability down to an individual patient may be required.

Tasks of further distributors

Secondary distributors include trade intermediaries, pharmacies and other points of dispensation. They are obliged to collect complaints and information regarding the use and efficacy of medical devices and transmit these to the relevant initial distributor. Further, they are obliged to carry out withdrawals/recalls and other safety measures directly or to forward corresponding information to the individuals concerned (e.g. professional users, patients).

Given the aforementioned duties, it is highly advisable that initial distributors (importers) conclude according agreements with their suppliers and/or manufacturers to arrange for access to the technical documentation, which is requested by authorities and to define the responsibilities with regard the product surveillance system.

Further, secondary distributors and the respective initial distributors should define and document a process to ensure that complaints and information on relevant experience are forwarded without any delay to the responsible distributor, importer or manufacturer. The respective responsibilities should be outlined in the respective agreement. This avoids any lack of clarity in the communication and collection of information and in the implementation of safety measures.

c. Germany

There is no specific requirement for the conclusion of Distribution Agreements in German law differing from other types of agreements. Distribution Agreements neither need approval by the government nor do any special requirements exist as to their form of a Distribution Agreement.

d. Argentina

Civil and Commercial Codes do not contain specific provisions/approvals for distribution agreements. Thus, there are no specific differences.

Incoterms

The following describes the role of Incoterms with respect to the Distribution and which Incoterms are usually used.

a. France

Incoterms vary from one agreement to another depending on the parties' interests. The most frequently used however are DAP or EXW. In the first case, the supplier bears the costs and risks during transport, while in the second case costs and risks are borne by the distributor as soon as the products leave the supplier's premises.

b. Switzerland

If the supplier is responsible for arranging carriage and delivering the goods at the named place, cleared for import and all applicable taxes and duties paid (e.g. VAT, GST) and therefore placing the maximum obligation on the supplier (DDP), he is responsible for import clearance and payment of taxes and/or import duty. This can be highly problematical for the supplier under the strict regulatory regime in Switzerland with regard to medical devices and products. It will always be in the supplier's interest to shift the according duties/risk to the distributor/customer, who rather has (or should have) the local knowledge.

FCA and CPT are interesting from a supplier's perspective as the duties and risks associated with clearance and distribution of (any) products in Switzerland are shifted to the distributor/customer.

The Incoterms agreed upon by the parties of a Distribution Agreement have significant consequences for the parties' duties with respect to observation of the Swiss regulatory regime. However, the importance of Incoterms should not be overrated. In the end, the consequences of the Incoterm selected will certainly be taken into consideration with regard to the parties' residual obligations (price, liability) and find the according reflection in the Distribution Agreement.

c. Germany

Incoterms are widely used in international trade. There is no specific term typically used in respect to the Distribution, the choice of a specific term is rather a matter of negotiation. However, the use of the term FCA has been frequently observed

d. Argentina

In national Distribution Agreements, Incoterms are not commonly used. However, in international Distribution Agreements, the most common Incoterms used are for air transport FCA and for ship transport FOB.

Clientele Compensation

The following outlines under which circumstances customers are entitled to clientele compensation.

a. France

Unlike agents, distributors are not entitled to any general compensation for the loss suffered at the end of their contract (be it fixed-term or open-ended) as a matter of principle. However, a distributor may claim damages in case of sudden termination of their contract if the notice period granted (in writing) is deemed to be too short, mainly in view of the length of the relationship.

If the notice period is deemed insufficient, damages are calculated on the basis of the gross margin that the terminated party would have made during a reasonable notice period, i.e., the gross margin they would have earned during a period of time corresponding to a reasonable notice period, minus the actual notice period they were granted.

Moreover, while the amount of compensation is usually calculated on the basis of the relationship' duration, it may be increased in case of "aggravating" circumstances. For instance, the court may take into consideration the existence of a state of economic dependence vis-à-vis the supplier or exclusivity between the parties to increase the amount of compensation. Likewise, if the distributor has to lay off part of their staff upon termination of the relationship, the court may hold the supplier liable for the payment of severance pay if the distributor can prove that the lay-off and the sudden termination are directly related.

b. Switzerland

In general, clientele compensation must be agreed upon in the Distribution Agreement. However, under certain conditions a distributor is entitled to clientele compensation, even if an according provision was not included in the Distribution Agreement. This view was adopted by the Federal Supreme Court, with reference to the agent's rights under commercial agency law. The following conditions need to be fulfilled:

- the distributor is integrated in the supplier's sales organization to a certain degree (e.g. in case of: minimum purchasing obligation; supplier's right to conduct price adjustments; supplier's right to cease production of a certain product; extensive promotion duties of the distributor; information duties of the distributor regarding sales; distributor's duty to report sales figures);
- the distributor has established an own or significantly increased his existing customer base/clientele during the term of the Distribution Agreement;
- the distributor's customers are virtually handed over to the supplier when the Distribution Agreement is terminated (e.g. in case of: distributor's duty to provide a list of his customers to the supplier; distribution of well-known brand products (so-called suction effect of a brand product)); and
- taking all relevant circumstances into account, a compensation does not seem inadequate.

If the above conditions are met, the distributor's entitlement to clientele compensation is compulsory and cannot be waived by an according provision in the Distribution Agreement. It is however possible, to specify the criteria regarding calculation of the (potential) clientele compensation in advance.

c. Germany

The German case law has a long tradition of applying the provisions of the German Commercial Code (*Handelsgesetzbuch*) on commercial agents, including the agent's right to compensation for clientele under sec. 89b of the Commercial Code, analogously to distribution agreements.

Firstly, the analogous application requires that the level of the distributor's integration in the distribution network of the supplier is comparable to the agent's. Secondly, the distributor must have a contractual duty to transfer its clients to the supplier after termination of contract.

If the requirements for the analogous application are met, the distributor is generally entitled to compensation, provided that the conditions stipulated in sec. 89b of the Commercial Code are fulfilled. Those are:

- The supplier considerably benefits from the client base developed or extended by the distributor after termination of contract.
- The payment of compensation is equitable under the circumstances of the case in particular the commissions lost as a result of the termination of contract.
- The contract is not terminated by the distributor (except with sufficient cause) and, if the contract is terminated by the supplier, the termination is not the result of misconduct by the distributor.

d. Argentina

A customer is entitled to clientele compensation only when the parties agreed upon in the contract.

Product Liability

The following outlines the applicable product liability regime.

a. France

Article L5121-8 section 6 of the French Public Health Code provides that: “Performance of the formalities provided for in this article [i.e., the formalities to obtain a marketing authorization] does not exempt the manufacturer and, if different, the holder of the marketing authorisation from their respective ordinary law liability with respect to the medicine's production or market release.”

The said article identifies two potential civilly liable parties: the MA holder (which is liable for releasing the drug onto the market) and the manufacturer, although pharmaceutical traders may also share liability. The ordinary law liability which article L5121-8 section 6 of the French Public Health Code refers to is that which forms the basis of the duty to redress the injury suffered by a patient/consumer due to the use of a medicine. Medicinal product liability is governed by articles 1386-1 et seqq. of the French Civil Code (which transposed the product liability directive of 25 July 1985). Accordingly, “the producer is liable for any injury caused by a defective product, whether or not they are bound to the injured party by contract”. »

It is therefore necessary to define the concepts of a defective medicinal product, of a producer, and of putting a product into circulation.

- Defective medicinal product: According to article 1386-4 of the French Civil Code, a “defective” medicinal product “does not offer the level of safety that can be rightfully expected”. The safety level that can be rightfully expected is appreciated according to the product information made available to the authorities concerned, to health professionals, and to patients. The duty to inform lies with the MA holder and the pharmaceutical trader. For instance, if the pharmaceutical trader is different from the MA holder, the former may incur liability alongside the latter inasmuch as the information on the drug that is being analysed in order to determine whether the product offers “the level of safety that can be rightfully expected” depends in

part on how the information pertaining to any adverse drug reactions reported after the drug was put into circulation is processed (Cour de Cassation, 1st civil division, 24 January 2006, no. 02-16.648; Cour de Cassation, 1st civil division, 24 January 2006, no. 03-20.178).

- **Producer:** According to article 1386-6 of the French Civil Code, the manufacturer of an end product, of a raw material, or of a component is deemed to be a producer and therefore to be liable when acting in a professional capacity. As a consequence, any person taking part in the medicinal product manufacturing process incurs liability, including such persons as have only partially contributed to the manufacturing process. However, the manufacturer, which in pharmaceutical regulations is defined as the mere performer of the MA dossier, should not theoretically be deemed to be a “liable producer” in the meaning of article 1386-6 of the French Civil Code provided the manufacturing process does not deviate from the specifications contained in the MA dossier. Where the defective medicinal product does not offer the level of safety that patients may rightfully expect and the manufacturer is not guilty of any negligence with regard to the manufacturing process, only the MA holder can be held liable (Cour de Cassation, 1st civil division, 24 January 2006, no. 02-16.648). Finally, pharmaceutical traders can also be deemed to be “liable producers” in the meaning of article 1386-6 of the French Civil Code if they fail to relay the pharmacovigilance information that they have a duty to process with sufficient efficiency.
- **Putting the product into circulation:** According to article 1386-5 of the French Civil Code, “a product is put into circulation when the producer willfully releases it”. Putting a medicinal product into circulation is the work of multiple pharmaceutical operators: at the top of the chain, the MA holder, which designs the product and its specifications, the manufacturer, which manufactures and releases the drug after certifying its conformity to the MA dossier, and finally, the pharmaceutical trader, which, after the drug has been validated from a technical standpoint by the manufacturer, injects it from an economic standpoint into the distribution chain leading to patients. According to the Court of Justice of the European Communities, which issued a preliminary ruling in the *O’Byrne v. Sanofi Pasteur* case, “a product is put into circulation when it is taken out of the manufacturing process operated by the producer and enters a marketing process in the form in which it is offered to the public in order to be used or consumed” (CJEC, 09 February 2006, case C-127/04, *Declean O’Byrne v. Sanofi Pasteur*). The product must be “taken out of the manufacturing process”, which corresponds to the manufacturer's decision to release the batch, and must “[enter] a marketing process”, which corresponds to the pharmaceutical trader selling the product.

b. Switzerland

The Federal Product Liability Act (SR 221.112.944) provides for strict liability (without default) of the manufacturer/producer of the defective product. The manufacturer is (primarily) the person that produced the (end) product, a basic material or a component product. Further, every person who declares to be the manufacturer/producer of the product by placing her name, trademark or any other distinctive mark on the product, is a manufacturer in terms of the Product Liability Act. Furthermore, any per-

son who introduces a product for the purpose of sale, lease or lease-purchase or any other of distribution, is deemed a manufacturer.

A condition for liability of the manufacturer is defectiveness of the product. A product is defective if it does not provide the safety which one is entitled to expect under the circumstances of the particular case. Whenever the (possible) defectiveness of a product is assessed, the following factors need to be taken into consideration:

- the way the product is presented to its potential customers;
- the use of the product that is reasonably foreseeable for the manufacturer; and
- the point in time at which the product is put on the market;

This means that a product is not defective for the sole reason that an improved version of the product is put on the market at a later point in time. However, product liability is a strict liability of the manufacturer without default being a condition of the latter's liability. Defectiveness of the product is sufficient. However, the Product Liability Act provides for a number of exceptions. The manufacturer is not liable if he proves that:

- he has not put the product on the market;
- the defect that has caused (any) damage did not exist when the product was put on the market by the manufacturer;
- the product was neither produced for the purpose of sales or any other form of distribution with an economical purpose nor was it produced or distributed in the course of the professional activity of the manufacturer;
- the defects are put down to the fact that the product was put in line with statutory governmental provisions; and
- that the defect could not be detected in accordance with the state of the art in science and technology at the time when the product was put on the market.

In accordance with the above definitions, apart from the "classic" manufacturers, a physician or a hospital are also manufacturers if they import pharmaceuticals or medical devices to Switzerland and put it on the market. In this context, it might be interesting to note that a manufacturer in terms of the Product Liability Act is not congruent with an initial circulator in terms of the Therapeutic Products Act. This means that a person can be deemed manufacturer in terms of the Product Liability Act without being an initial circulator in terms of the Therapeutic Products Act (HMG) or Ordinance on Medical Devices (MepV) respectively.

In practice, there are numerous situations where e.g. a hospital is deemed a manufacturer in terms of the Product Liability Act and is therefore liable for defectiveness of a certain product. This is an important fact that is – depending on the nature of the product in question – likely to be reflected in a Distribution Agreement. With regard to Product Liability, a distributor/customer in particular should consider to have a broad respective section included in the Distribution Agreement, which covers all aspects of his potential liability.

c. Germany

The applicable product liability regime is the German Pharmaceuticals Act (*Arzneimittelgesetz*). Sec. 84 following of the German Pharmaceuticals Act provide for a strict liability of any trader of pharmaceuticals for the damage suffered to the health or life of a person as a result of the application of a medicinal product regardless of negligence. The product liability regime of the German Pharmaceuticals Act also includes a shift of burden of proof under certain circumstances.

d. Argentina

According to Argentine Consumers Law No. 24,240, the term for a consumer to bring an action against the distributor and/or supplier would elapse after three years, the term for other players in the commercialization chain who have a direct contractual relationship with the distributor and/or the supplier (e.g. retailers who have acquired the goods from the distributor and/or the distributor's subcontractor) would expire only after ten years. In any event, the contractors may be interested in considering the possibility of counting the three-year term from the date of expiration of the Products instead of considering the date of termination of the Agreement (e.g. the product might be stored and not sold for a while and the mentioned 3-year expiration shall be therefore delayed).

Intellectual Property

The following describes how the Distribution Agreement's parties protect their respective IP.

a. France

In general the parties protect their IP rights via licensing agreements or warranty clauses in the Distribution Agreements.

b. Switzerland

Medical inventions are usually protected by according patents. The data that is generated in the course of the approval process of pharmaceuticals to the Swiss market is subject to protection of the so-called first applicant and cannot be accessed by competitors for a certain period of time. The protection of the first applicant and its duration exist regardless of the existence of the respective patent and its term of protection. The protection of the first applicant obliges the competent authorities to protect the relevant confidential documentation and research data (submitted by the first applicant in the course of the approval process) from being disclosed to and/or being unfairly used for commercial purposes by third parties.

Trademark protection includes the (typical) right to use a trademark for identification/labelling of products and services and to have the trademark at one's disposal.

As the supplier usually has an interest to maintain its IP-rights – not only because of the significant cost associated with the development of a certain product – the distributor will usually not claim any participation in such rights.

Accordingly, property and use of patents, trademarks, designs and know-how are reflected in the Distribution Agreements:

- Intellectual property is usually defined in the definitions section of the Distribution Agreement in a very broad manner, e.g. as follows: “Intellectual Property”: All or any of the following: “Trademark” (“XX” as registered in [...], Register No. [...]), “Patents” (relating to the product), “Know-how” (relating to the product), “Designs” (relating to the product).
- As protection of intellectual property is usually solely in the supplier’s interest, the following provision is usually included in the Distribution Agreement: “The Parties agree that the Supplier maintains the Intellectual Property during the whole term of this agreement.”

c. Germany

The protection of intellectual property is generally ensured by inserting a licence agreement which determines the form and the extent of use of trademarks and other intellectual property. Further, the protection of know-how is secured by a non-disclosure agreement enforceable by liquidated damages for any case of its violation.

d. Argentina

The supplier shall obtain and renew registration of the products’ trademarks in the territory. Besides, the supplier should include a clause in the agreement stating that the trademarks are of its own property and that customer only can use them to the extent granted by supplier in the agreement while it's still in force. Moreover, the distributor should protect the supplier's trademarks.
