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THE DISTRIBUTION OF PHARMACEUTICAL AND MEDICAL DEVICES - OR HOW ARNOLD SCHWARZENEGGER BECAME THE TERMINATOR

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Introduction

Pharmaceuticals and medical devices are subject to a strict regulatory regime. Manufacturers/sellers have to observe comprehensive security and other provisions whenever medical devices/products are put on the market in Switzerland.

Before medical products can be put on the Swiss market, tests regarding quality, safety and effectiveness have to be performed. For this reason, medical products go through a so-called marketing authorization process and are put into various supply categories. The supply category specifies the authorization to supply a certain medical product. The categorization of medical products therefore has direct economic consequences for manufacturers and sellers. This issue has always been in the center of political interest.

1. Latest Novelties and/or Developments

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;
- Examination of the institutional framework.

The following areas are concerned by the upcoming revision:

- Medicinal products for paediatric 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;
- Benefits of monetary value.

In particular the underlined areas above are likely to have an impact on the Distribution and the future arrangement of Distribution Agreements. The current status is (partially) outlined below (clauses 2 and 7).

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

2. Legal Framework

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);
- 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 [MRA]). 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 and 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).

3. Building Blocks

In general, the provisions of a Distribution Agreement are the following (the Blocks marked [*] are only applied occasionally):

- 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
- * Power of representation: distributor's appointment conclude sales of product(s) on behalf of the supplier;
- * Exclusivity: distributor's right to distribute the product exclusively in a certain territory;
- * Minimum performance: whenever exclusivity is agreed upon, the distributor will be obliged to purchase a minimum quantity of the product(s);
- Intellectual Property: protection of existing trademarks, patetents, etc. (see below, clause 11);
- Consignments: acceptance/delivery/payment
- 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;
- Governing law/jurisdiction

4. Form and Formalities

In general, 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 (see clause 7).

5. Important Provisions

The principal/supplier will have a particular interest to have the following provisions included in a Distribution Agreement:

- 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 (see clause 11);
- Protection and promotion obligations of the distributor;
- Distributor's obligation to abstain from purchasing/supplying competitive products;
- Shifting of regulatory obligations with regard to products to the distributor (to the extent possible).

The distributor/customer will have a particular interest to have the following provisions included in a Distribution Agreement:

- 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);
- Customer protection.

6. Continued Supply

It is not unusual that a customer/distributor 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 distributor's right must be combined with according exemptions from possible loyalty and non-compete clauses in this particular case.

7. Specific Provisions

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

a. 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[1]. 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;

[1] Art. 3 para. 2 MepV

- Ensure that the following restrictions are observed with regard to:
  - Certain products are subject to prescription (e.g. medical devices which contain a pharmaceutical subject to prescription, 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;
- 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).

b. 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[2].

1. 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 ditributor 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.

[2] Art. 14 et seq. MepV

2. 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[3].

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.

8. Incoterms

With a strict regulatory environment as the one before us, the Incoterms 2010 can be of significant importance.

E.g., 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 [Delivered Duty Paid]), 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 (see above). It will always be in

[3] Section 5 MepV: Product surveillance, Reporting of incidents and safety measures

the supplier's interest to shift the according duties/risk to the distributor/customer, who rather has (or should have) the local knowledge.

The Incoterms FCA (Free Carrier, Place named) and CPT (Carriage Paid To) are interesting from a supplier's perspective as the duties and risks associated with clearance and distribution of (any) products in Switzerland is 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.

9. Clientele Compensation

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[4]. 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 establish an own or significantly increased his existing customer base/clientele during the term of the Distribution Agreement;

[4] Decision 134 III 497 of the Federal Supreme Court

- 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]);
- Taking all relevant circumstances into account, a compensation does not seem inadequate.

If the above conditions are met, the distributor's/customer'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.

10. Product Liability

Specific liability regulations with regard to defective medical products are unknown to the Swiss medical device law. The general liability provisions of Swiss substantive law are applicable.

The (Federal) Product Liability Act (PrHG; 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[5]. 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 person who introduces a product for the purpose of sale, lease or lease-purchase or any other of distribution, is deemed a manufacturer[6].

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

[5] Art. 2 para. 1 lit. a PrHG
[6] Art. 2 para. 1 lit. b and c PrHG

circumstances of the particular case[7]. 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;
- 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[8]. 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;
- 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 a 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 a initial circulator

[7] Art. 4 para. 1 PrHG

[8] Art. 5 PrHG

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.

11. Intellectual Property

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 overwhelming interest to maintain his IP-rights – not only because of the significant cost associated with the development of a certain product – the distributor/customer 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."

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