



INTERNATIONAL ASSOCIATION OF YOUNG LAWYERS

WORKING SESSION ON

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

AIJA Annual Congress 2015 – London

National Report of Germany

Babak Tabeshian

ARIATHES Rechtsanwälte
Prinzregentenplatz 14,
81675 Munich, Germany
+49 (0)89 980314
tabeshian@ariathes.eu

General reporter:

Moritz Maurer
Pestalozzi, Zurich, Switzerland

2.1 Latest Novelties and/or Developments

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.

2.2 Legal Framework

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 (Medizinproduktgesetz).

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.

2.3 Building Blocs of Distribution Agreements

A typical Distribution Agreements may be structured as follows:

- a. Appointment of Distributor
Definition and scope of distribution (eg exclusivity)

- b. Subject-matter of contract
Description of the (category of) products that are subject to distribution
- c. Contractual area
Definition of the sales area
- d. Rights and duties of the Distributor
 - Right and duty to market and promote sales
 - Definition of sales channels
 - Duty to develop promotional activities
 - Duty to report
- e. 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
- f. Regulatory issues and product recalls
 - Definition of responsibilities for regulatory issues (eg admission of pharmaceuticals)
 - Definition of duties in case of product recalls
- g. Sales targets
 - Specification of sales targets
 - Consequences of non-compliance with sales targets (eg termination of exclusivity and/or contract)
- h. 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
- i. Intellectual property
Subject matter and scope of Distributor's right (licence) to use the trademarks of the Supplier in the course of his sales activities
- j. Term and Termination of contract
Duration of contract and conditions of premature termination
- k. Effects of termination
 - Cessation to use trademarks
 - Conditions of sale of remaining stocks

- l. Indemnification and liabilities
 - Limitation of liability of the Supplier
 - Distributor's duty to indemnify and hold harmless the Supplier against claims of third parties
- m. Non-compete clause
- n. Confidentiality clause
- o. General provisions

2.4 Form and Formalities

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.

2.5 Important Provisions

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 Supplier has an interest to ensure to receive an indemnification upon termination of contract.

2.6 Continued Supply

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.

2.7 Important Provisions

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.

2.8 Incoterms

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.

2.9 Clientele Compensation

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 extend 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.

2.10 Product Liability

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.

2.11 Intellectual Property

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.