



INTERNATIONAL ASSOCIATION OF YOUNG LAWYERS

**WORKING SESSION ON**

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

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**National Report of Argentina**

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## 2.1 Latest Novelties and/or Developments

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 August 1, 2015.

## 2.2. Legal Framework

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.

In Argentina, the most relevant rules regarding Distribution of pharmaceuticals are the following:

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

## 2.3 Building Blocks

1. Legal Identity of the Parties.
2. Appointment of Distributor:



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- a. Specify whether it's exclusive or non-exclusive;
  - b. Set forth territory; and
  - c. Permit or prohibit appointment of sub-distributors.
3. Term.
  4. Define Products and reservation of rights.
  5. Pricing terms (e.g. initial, notice for changes).
  6. Terms of Payment (e.g. Currency, Letter of Credit).
  7. Performance requirements (e.g. sales targets, remedial measures, forecast).
  8. Procedures related to Ordering and Shipping (e.g. risk allocation, traceability).
  9. Supplier's Responsibilities (e.g. min. & max. order, technology support, marketing, recall).
  10. Distributor's Responsibilities (e.g. inventory, reporting, training, cold chain, recall, good practices).
  11. Government filings or approval (allocation of responsibility, registration of Distributor).
  12. Warranty (defective product procedure, returns).
  13. Intellectual Property rights (e.g. parties' rights, granted and reserved).
  14. Termination (e.g. renewal, special circumstances).
  15. Non-Circumvention & Confidentiality.
  16. Assignment.
  17. Post-Termination Rights.
  18. Dispute Resolution process.
  19. Non-compete provisions.

## **2.4 Form and Formalities**

Argentine Law requires no particular form or formalities for this type of agreements. However, written contracts are the most common form of agreements.

## **2.5 Important Provisions**

All parties:

- a) 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



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including acts of law/change in law and government acts within the scope of force majeure of the Agreements.

b) Insurance of products

Supplier:

a) Payment (if international, without taxes, provisions to receive full amount with no deduction or withholding).

b) Currency (due to unstable of Argentine Pesos, its important to establish it and price increase if necessary).

c) Product Recall

d) Lead Time

e) Delays

f) Stock conditions

Customer:

a) Returns

b) Product registration

c) Defective product

d) Product samples

e) Clientele Compensation

## **2.6 Continued supply**

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.

## **2.7 Specific Provisions**



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As I mentioned before, Civil and Commercial Codes does not contain specific provisions/approvals for distribution agreements.

## **2.8 Incoterms**

In national distribution agreements, Incoterms are not commonly used. However, in international distribution agreements, the most common Incoterms used are the following:

For air transport:

FCA: FREE CARRIER

For ship transport:

FOB: FREE ON BOARD

## **2.9 Clientele Compensation**

Customer is entitled to clientele compensation only when the parties agreed in the contract.

## **2.10 Product Liability**

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).

## **2.11 Intellectual Property**

Supplier shall obtain and renew registration of the products' Trademarks in the Territory. Besides, supplier should include a clause in the agreement stating that the Trademarks are of its



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own property and that customer only can use them to the extent granted by supplier in the agreement while its still in force. Moreover, customer should protect suppliers trademarks.