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 for France

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1. Latest novelties and/or developments

In order to allow the sale of medicinal products on the internet, France transposed EU directive no. 2011/62 of 08 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included in the list of medicines available in pharmacies ("liste de médication officinale") could be sold online, was rescinded (Conseil d'État, 17 July 2013, nos. 365317, 366195, 366272, 366468).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Finally, the ministerial order of 20 June 2013 was also challenged before and rescinded by the Conseil d'État (Conseil d'État, 16 March 2015, nos. 370072, 370721, 370820) because it exceeded the scope of the powers devolved to the Minister by law.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.

2. Legal framework

2.1 Operators

Unlike normal distribution channels, the drug supply chain is (not surprisingly) heavily regulated. It involves a number of operators whose remits are clearly defined in article R5124-2 of the French Public Health Code.

2.1.1 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).

a. 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 – or 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).

b. Pharmaceutical traders ("exploitants")

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

Pharmaceutical companies can take on the role of pharmaceutical traders, in which case they, too, are authorised to store and wholesale their drugs to distributors or community pharmacies.

2.1.2 At wholesale distribution level

Under French law, 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.

a. 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.

b. 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.

c. 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.

2.1.3 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.

a. 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).

b. 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.

2.2 The various types of drug distribution agreements

2.2.1 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.

2.2.2 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.

2.2.3 Agreements between pharmaceutical companies and groupings of community pharmacies

a. 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.).

b. 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.

2.3 Regulatory framework

2.3.1 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.

2.3.2 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.

2.3.3 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.

3. Building blocks

Distribution agreements (no agency) 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,
- term, termination, and consequences of termination,
- applicable law and jurisdiction.

4. Form and formalities

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 01 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 "business 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.

In 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[1] 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.

5. Important provisions

5.1 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.

5.2 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.

[1] « Bonnes pratiques de distribution en gros des médicaments à usage humain », Agence nationale de sécurité du médicament et des produits de santé, Bulletin officiel Santé, protection sociale, et solidarité, no. 2014/9bis

6. Continued supply

6.1 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,
- to take turns to be on call during weekends and public holidays.

6.2 Emergency call centres

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 centres 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 centres 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).

7. Specific provisions

7.1 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.

7.2 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.

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.

8. Incoterms

Incoterms are used to easily identify (i) the exact moment when the transfer of risks occurs when products are sold from supplier to distributor and (ii) the party that bears the transport costs when a product is sold.

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.

9. Clientele compensation

9.1 Unlike agents[2], 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.

9.2 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.

[2] If an agency agreement is terminated by the principal, the commercial agent is entitled to compensation for the loss suffered, bearing in mind that the French courts generally assess such loss as amounting to two years' gross commissions calculated on the basis of the average yearly commissions received over the last three years.

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.

10. Product liability

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 (**10.1**), of a producer (**10.2**), and of putting a product into circulation (**10.3**).

10.1 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[3], 1st civil division, 24 January 2006, no. 02-16.648; Cour de Cassation, 1st civil division, 24 January 2006, no. 03-20.178).

[3] France's highest civil court.

10.2 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.

10.3 Putting the product into circulation

According to article 1386-5 of the French Civil Code, "*a product is put into circulation when the producer wilfully 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.

11. Intellectual property rights

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

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