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Alexander Ehlers

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GETTING THE DEAL THROUGH

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France

Christophe Henin and Anne Servoir
Intuity

Organisation and financing of health care

1 How is health care in your jurisdiction organised?

The French health-care system is based on the principle of free patient choice. People can decide to visit their assigned doctor, a specialist in direct access, or a public or private health establishment.

However, the health system is controlled to a large extent by the state across three different levels to ensure that it is consistent, especially in times during which the social security system and corresponding budget are affected by huge deficits.

At the national level, the state is directly involved in the financing (social security system) and organisation of the health-care system delivery, and consequently promotes uniform national coverage and an effective match between the different stakeholders.

The regional health agencies (ARS) are organised at a regional level to ensure consistent resource management and relevant coordination at the regional level. They adapt national policies to regional contexts through regional health programmes composed of regional plans for prevention within hospital or private practice, as well as socio-medical schemes provided for elderly or dependent patients.

At the local level, structures and health professionals are organised under the supervision of the ARS to allow optimal management of patients according to their health status: primary health care provided by a general medical practitioner providing referrals, or secondary health care provided by medical specialists and health facilities. This organisation relies on health-care coordination between health facilities and primary care on the one hand, and a continuous ambulatory or hospital care reinforcement on the other.

2 How is the health-care system financed in the outpatient and in-patient sectors?

The French health-care system is financed by personal and social contributions, as well as several taxes borne by companies, such as pharmaceutical companies, active within the system.

The main sources of funding (78.8 per cent in 2012) resulting from social security contributions paid by all individuals. Other funding sources are quite diverse, such as taxes (VAT for pharmaceutical and health products, taxes on promotion, direct sales, turnover, etc).

The French system does not distinguish between outpatient and in-patient sectors in terms of the financing and coverage of health expenses.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and health-care professionals?

In France, advertising for medicinal products is governed by provisions of the French Public Health Code (PHC), which comply with the relevant provisions of modified Directive 2001/83/EC on the Community Code relating to medicinal products for human use.

The advertising guidelines of the French National Agency for Medicines and Health Products Safety (ANSM) shall also be taken into account.

The pharmaceutical industry is also bound by the Code of practice on representatives in pharmaceutical products, signed between the professional organisation of the pharmaceutical industry (LEEM), the Economic Comity for Medicinal Product (CEPS) and the Code of practice on the communication of pharmaceutical companies on the internet (signed between the LEEM and the ANSM). As the LEEM has signed the European Pharmaceutical Industries and Associations (EFPIA) Code of practice on the promotion of medicines, each pharmaceutical company and member of the LEEM must also respect all the provisions of the EFPIA Code.

Pharmaceutical companies are also bound by the Consumer Code, which prohibits misleading or comparative advertising and is applicable to any type of product.

4 What are the main rules and principles applying to advertising aimed at health-care professionals?

The main rules and principles applying to advertising aimed at health-care professionals are provided by articles L5122-2–L5122-5, L5122-9–L5122-12 and R5122-8–R5122-17 of the PHC, which state the following:

- the advert must not be misleading and must not present a risk to public health. The presentation of the medicinal product must be objective and encourage its proper use;
- the advert must comply with the provisions of the marketing authorisation, and with the information contained in the summary of the medicinal product characteristics;
- the advert must indicate a minimum level of information such as the name of the product, the name of the manufacturer, the product's pharmaceutical form, its administrative form, its dosage, its therapeutic indications and contraindications, adverse reactions, special warnings and precautions for use, medicinal and other interactions, and the status regarding reimbursement by the health-care system;
- the information provided must be accurate, updated, verifiable and sufficiently exhaustive to enable health-care professionals to make their own judgements on the therapeutic value of the product; and
- each chart, quotation or illustration taken from medical journals or scientific literature must be quoted faithfully. Their source must be precisely stated. Any written mention thereof must be clearly legible.

Since the enactment of Law 2011–2012 of 29 December 2011 and its implementation decrees, advertising for medicinal products intended for professionals – as in the case of advertising to the public – must be previously authorised by the ANSM. Failure to comply with this obligation constitutes a breach subject to a financial penalty.

The ANSM may impose, as such, an administrative penalty that shall not exceed 10 per cent of the annual turnover or €1 million.

The oral presentation of a medicinal product should only be delivered by medical sales representatives, who shall have specific diplomas and sufficient scientific knowledge that is regularly updated, and shall include a summary of the medicinal product characteristics, the classification of the product, its maximum selling price, its possible reimbursement, the daily treatment cost and the approval of public institutions. This practice is also framed by the Code of practice on representatives in pharmaceutical products.

5 What are the main rules and principles applying to advertising aimed at the general public?

Advertising of medicinal products intended for the public is only allowed under the following conditions:

- the product is not prescribed;
- none of its presentations is refundable by the social security scheme; and
- the marketing authorisation does not contain prohibitions or restrictions as regards advertising intended to target the public.

In addition, the advert must not be misleading and must not present a risk to public health. The presentation of the medicinal product must be objective and encourage its proper use, and must comply with the provisions contained in the marketing authorisation and the summary of the medicinal product characteristics.

Such advertising must be conceived so that the character of the advertising message is obvious and the product is clearly identified as a medicinal product.

Any advertising for a medicinal product intended for the public must comply with the provisions of the Consumer Code and shall also contain:

- the denomination, as well as the INN when the product contains only one active ingredient;
- any essential information for proper use;
- an express invitation to read the leaflet; and
- a message of caution, and a reference to the advice of a pharmacist and to the consultation of a medical practitioner.

Finally, advertising for medicinal products intended for the public shall be previously authorised by the ANSM. Failure to comply with this obligation constitutes a breach subject to a financial penalty.

The ANSM may impose, as such, an administrative penalty that shall not exceed 10 per cent of a company's annual turnover or €1 million.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

The most common infringements committed by manufacturers are breach of the Consumer Code provisions with regards to misleading or comparative advertising. The ANSM often issues decisions banning advertising that fails to fulfil the provisions of the marketing authorisation, or that constitutes indirect advertising that was not previously authorised pursuant to the law.

7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

According to article L5122-2 of the PHC, advertising of medicinal products must comply with a marketing authorisation. Pharmaceutical companies are under an obligation to refer to the ANSM off-label use practices.

Accordingly, advertising on off-label use of medicinal products is not permitted and is punishable by up to two years' imprisonment and a fine of up to €30,000 (article L5422-1 of the PHC).

However, Law No. 2011–2012 of 29 December 2011 has allowed off-label use of medicinal products by prescribers when an authorised, appropriate alternative medicinal product does not exist and when:

- the physician duly considers that such a prescription is essential for his or her patient; or
- the ANSM has adopted a recommendation for therapeutic use (RTU) stating therapeutic indications or conditions of use. This recommendation, whose validity may not exceed three years, includes providing the necessary information to the prescriber for assessing the proper medicinal administration (such as dosage, adverse effects), and is published on the website of the ANSM.

8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals? Do different rules apply regarding physicians in the outpatient and in-patient sectors?

In France, such a relation is strictly regulated by the Health Professions Council and the Social Security Code.

In addition, pharmaceutical companies that are members of the LEEM shall fulfil the provisions provided by the Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations. Adopted on 24 June 2013, this Code will come into force in 2016.

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

Heath-care professionals, including physicians, pharmacists and medical students, cannot receive any direct or indirect advantage, in kind or in cash, except for:

- advantages provided by an agreement whose express subject and real purpose are research activities or scientific evaluation. The agreement should be submitted before its implementation to the departmental council of the relevant professional body, and compensations should not be calculated on the basis of the number of prescribed services or products;
- hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes when provided by agreement between the company and the health professional, and submitted before its implementation to the departmental council of the relevant professional body. This hospitality should be reasonable and limited to the main scientific and professional objective of the event. Such hospitality cannot be extended to persons other than the professionals directly involved; and
- gifts of negligible value, relating to the exercise of their activity.

Failure to comply with this provision is a criminal offence punishable by up to two years' imprisonment and a fine of up to €75,000.

Thus, pharmaceutical companies are also required to make public the existence of agreements with health professionals and advantages granted for an amount at least equal to €10.

Article R1453-3 of the PHC provides for mandatory transparency and the publication of contractual relationships (the identity of both parties, the date of signature, the subject and purpose of the agreement, the nature of the benefit, the corresponding amount and, if applicable, the event programme) on the website of the pharmaceutical company or on a 'common site'. A deliberate failure of companies to comply with this publication is punishable by a fine of up to €75,000.

Furthermore, discounts, rebates and commercial and financial benefits, including commercial cooperation agreements on reimbursable medicinal products granted to pharmacists, may not exceed (for the calendar year and by product line) 2.5 per cent of the manufacturer's price excluding taxes, and 40 per cent for generic specialties, per pharmacy (since the Order of 22 August 2014 laying down limits for discounts, rebates and other commercial and financial benefits set out in article L138-9 of the Social Security Code). It is worth noting that pharmacists were previously eligible for generic discounts to the sole extent of 17 per cent. However, circumvention practices revealed by some 'hidden' discounts in the form of commercial cooperation agreements encouraged the government to raise this limit up to 40 per cent.

10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

Due to the recent modification of the law and corresponding provisions mentioned above, pharmaceutical companies are experiencing difficulties in portraying their contractual relationship with health-care professionals, properly framing their global relationship with hospitals and their physicians, and orientating such possible close relations in a way that might induce anti-competitive behaviours.

11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

Beyond the EFPIA Codes mentioned above, provisions relating to the mandatory declaration of 'interests' described in question 9 duly apply to patient associations and pharmaceutical companies are under the obligation to declare the list of potentially financed patient associations (in total or in part).

12 Are manufacturers' infringements of competition law pursued by national authorities?

The French Competition Authority regularly condemns pharmaceutical companies for anti-competitive behaviours, and especially for abuse of a dominant position.

Thus, the Competition Authority recently fined a pharmaceutical company €40.6 million (Decision No. 13-D-11 of 14 May 2013) and another company €15.3 million (Decision No. 13-D-21 of 19 December 2013) for a denigration strategy implemented to prevent the entrance of generic competitors.

Another important and relevant case is under scrutiny, and a decision should be issued by the end of 2014.

It is worth noting that the Competition Authority issued Opinion No. 13-A-24 on 18 December 2013 relating to the functioning of competition in the distribution sector of drugs for human use 'in town' ('distribution in town' means distribution from pharmacists as opposed to distribution in hospitals) to regulate the denigration practices that are most common in France.

13 Is follow-on private antitrust litigation against manufacturers possible?

Violations of competition law and restrictive practices may be enforceable before the competent tribunal by competitors in order to potentially request corresponding damages. Parallel litigations are common to exercise greater pressure on the dominant pharmaceutical company before the Competition Authority, as well as before the tribunal, to immediately request damages.

Compliance – medical device manufacturers

14 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Law No. 2011–2012 of 29 December 2011 introduced a new regulation on advertising for medical devices, which is generally less cumbersome than the regulation in force governing medicinal products, except for those that might induce a significant risk to public health (a list is laid down by two decrees dated 24 September 2012).

Advertising is forbidden for medical devices that do not bear a certificate of conformity. In addition, the advertising shall describe objectively the product and, where applicable, its performance and compliance with essential requirements for safety and health. It must not be misleading, or present a risk to public health.

Finally, as under the relevant rules for reimbursed medicinal products, any advertising to the general public in favour of medical devices whose costs are supported at least partially by the national health system is strictly prohibited.

Pharmaceuticals regulation

15 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

In accordance with EU directives and regulations, the conditions to grant a marketing authorisation for human use (for innovated products as well as for generics), either nationally or through the centralised or decentralised procedure for human use, are contained and detailed within the PHC (articles L5121-8, R5121-21 and the following) and generic products (articles L5121-10, R5121-5 and the following).

16 Which authorities may grant marketing authorisation in your jurisdiction?

For many years, the French Health Products Safety Agency (AFSSAPS) has been the relevant health administrative body to grant marketing authorisations and enforce the rules applicable to medicines and pharmaceutical firms. It was replaced by the ANSM on 1 May 2012 following the publication of Decree No. 2012-597 on 27 April 2012. As a public body under the supervision of the Ministry of Health, the ANSM has taken over the tasks of the AFSSAPS, and has been entrusted with new powers and responsibilities.

17 What are the relevant procedures?

Applications for marketing authorisations are submitted to the ANSM, which scientifically assesses the marketing authorisation file according to scientific criteria regarding quality, safety and effectiveness. A new product must provide a benefit-to-risk ratio at least equivalent to existing products.

The application is thus reviewed by the committees of the ANSM (and in particular by the commission in charge of the initial assessment of the risk-to-benefit balance of the health products) if a deeper examination and a supplementary peer opinion for such a case is required. Three outcomes can arise: a favourable opinion, a request for further information or an unfavourable opinion.

The final decision belongs to the General Director of the ANSM. A simplified procedure exists for generics in full accordance with article 10 of Directive 2001/83/EC (modified).

Any company marketing medicinal products without prior authorisation incurs two years' imprisonment and a maximum fine of up to €30,000 (article L5421-2 of the PHC).

18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

The marketing authorisation for a medicinal product and the registration of certain products (such as homeopathic or herbal medicines) lapse if they are not marketed in the territory within three years following the authorisation or registration, or if the corresponding product is no longer on the market for three consecutive years.

The ANSM may grant exemptions to such an applicable rule, either for public health reasons or:

- when the medicinal product could not be legally marketed during the period;
- when the medicinal product was exclusively intended for export to a state that does not belong to the European Economic Area; or
- when the medicinal product is marketed in at least another member state of the European Union or of the European Economic Area while a different dosage or pharmaceutical form is marketed in France.

19 Which medicines may be marketed without authorisation?

Homeopathic medicines and traditional herbal medicines complying with the conditions respectively provided by article L5121-13 and article L5121 -14-1 of the PHC are only subject to registration and not to the rigorous formalism of the procedure applicable to the medicinal products for human use.

Medicinal products not industrially manufactured (pharmacy preparations, hospital preparations and pharmaceutical preparations) have their own regulatory rules that do not involve the obligation to register the preparation or to obtain a marketing authorisation.

In addition, it is worth mentioning the possibility to obtain a temporary authorisation for use (ATU) when a medicinal product – whose efficacy and safety is presumed within scientific knowledge – is intended to treat, prevent or diagnose serious or rare diseases and no other appropriate medicine exists.

The ATU is said to be 'nominative' when the product is prescribed at the request and under the responsibility of the prescriber and physician.

The 'cohort' ATU, referring to a group or sub-group of patients who are included within a clinical protocol for therapeutic use, might also be granted at the sole request of the holder of the corresponding rights concerned and under specific conditions.

20 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

As mentioned in question 19, such a legal possibility, contained in article 5(1) of Directive 2001/83/EC, follows the 'nominative' ATU regime.

Pricing and reimbursement of medicinal products

21 To what extent is the market price of a medicinal product governed by law or regulation?

In this regard, a key distinction has to be made between the hospital market for in-patients and the pharmacies market for outpatients:

- for the hospital market, pricing is free and prices are set through tender offers (except for medicines that can be also purchased by outpatients and for most innovative medicines for which maximum prices are set according to a procedure similar to the one applying to medicinal products reimbursable 'in towns');
- 'in towns' (pharmacists), the ultimate goal of the pharmaceutical company is to obtain a reimbursable price that might meet its internal costs and margins. In such a case, the price is then fixed in a contract signed between the pharmaceutical company and the CEPS. If the result of the negotiation does not fulfil the objectives of the company, then the company might decide not to market its medicinal product in France; and
- prices are free for over-the-counter products.

22 Must pharmaceutical manufacturers negotiate the prices of their products with the public health-care providers?

As mentioned above, depending on the market segment concerned, and especially 'in towns', the negotiation is centralised through discussion with the CEPS. This leads to a signing of contracts that shall also impose other obligations on the pharmaceutical company, such as maximum volumes to be sold or rebates to be paid to the health insurance system if these maximum volumes are exceeded.

23 In which circumstances will the national health insurance system reimburse the cost of medicines?

To be reimbursed, the product has to be listed within two lists – one for hospitals and the other one for pharmacies 'in towns' pursuant to article L162-17 of the Social Security Code. This registration is granted with respect to a single criterion: the therapeutic value, which is fixed for each therapeutic indication.

Reimbursement of prescribed off-label medicinal products is not excluded in cases strictly defined through the adoption of a ministerial order, and especially where no alternative treatment exists for a long-term illness or an orphan disease, and provided that the medicinal product is subject to a temporary RTU.

Off-label prescribed products might be reimbursed if they are precisely prescribed under the RTU regime, or in cases strictly defined of a 'nominative' ATU pursuant to Decree No. 2013-870 of 27 September 2013.

24 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

The cost of pricing reimbursable medicinal products is regulated and set by a convention between CEPS and the firm. The process takes into account various criteria set out in article L162-16-4 of the Social Security Code, including the improvement of clinical benefit evaluated through the Transparency Commission of the French National Authority for Health, prices of other medicinal products within the same therapeutic class, the expected or recorded sales volume, and the actual and foreseeable use of the medicinal product.

For generics, the price set out by the CEPS is systematically 60 per cent lower than a referenced medical product.

The reimbursement rate is decided by the President of the French National Union of Medical Insurances, and is then endorsed by a ministerial order and published in the Official Journal of the French Republic.

25 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

As mentioned above, rebates might be due to the national insurance system in specific circumstances: for example, where maximum volumes of sales (agreements on price and volume), provided in the contract between the CEPS and the pharmaceutical company, have been exceeded.

Article 138-10 of the Social Security Code subjects pharmaceutical companies to an overall contribution where expenses of reimbursable medicinal products exceed the growth rate of the national health insurance spending objective (fixed by the parliament) whenever the pharmaceutical company has refused to sign a contract with the CEPS; however, this happens very rarely.

Medicine quality and access to information

26 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

Order No. 2012-1427 dated 19 December 2012 and the Decree dated 31 December 2012 implement the provisions of Directive 2011/62/EU dated 8 June 2011.

These provisions introduced the definition of a falsified medicinal product and secured the distribution channel of medicinal products (notably, definition of the 'trader' of medicinal products, as well as information to be added on the external packaging of the medicinal product in order to ensure its integrity). They also limited sales through the internet to websites initiated and managed by pharmacists and previously authorised by the ARS, and to pharmacists who also have a pharmacy establishment (see the Order of 20 June 2013 on good dispensing practice for medicinal products).

27 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

A decree dated 27 September 2013 determined the creation (since 1 October 2013) of a public database of medicinal products, which collects administrative and scientific information on all pharmaceutical products (prescribed or not, reimbursed or not) on a single public website.

The information provided within the database includes the name of the product, its composition in active substances, a summary of the medicinal product characteristics, the package leaflet, the clinical or therapeutic value, and the sale price.

28 Outline major developments to the regime relating to safety monitoring of medicines.

No major pharmacovigilance reform has been introduced in France since the adoption of Law No. 2011–2012 dated 29 December 2011. However, two decrees were recently published in the Official Journal.

The first decree implements the provisions of Directive 2010/84/EU and enhances the powers of the General Director of the ANSM with regards to medicinal product safety. For example, it provides the means, following the granting of a marketing authorisation, to ask a company to carry out safety and efficacy studies, or to impose a risk management plan.

The second decree, dated 16 October 2013, transposes Directive 2012/26/EU dated 25 October 2012 in order to reinforce pharmacovigilance obligations on exporting companies to countries that are not members of the EU and on importing companies from these countries.

Vaccination

29 Outline your jurisdiction's vaccination regime for humans.

French vaccination policy is the responsibility of the Minister of Health, who must consult the High Council for Public Health, as well as a technical vaccination committee.

The vaccination regime, as in many other countries, distinguishes compulsory vaccines (such as tetanus and poliomyelitis) and vaccines solely recommended (such as pertussis, rubella, measles, mumps and chicken pox).

The procedure for setting the price and obtaining reimbursement for vaccines follows the medicinal product for human use regimes (see above).

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