

# The French Approach to Rx

By Hazelwood Wise

PARIS — France is a country of pharmacies, often more common place on a city street than boulangeries; their neon green signs are often the only thing noticeable on an otherwise subdued street.

With a population of 60 million and the second-largest economy in western Europe, France is vital to the cosmetics and pharmaceutical industries. Entry into this market, however, requires an understanding of European law.

But in this fledgling area of European legislation, until the upcoming European Directive on Pharmaceuticals is approved and fully implemented national legislation very often determines what may be sold in a given national market and whether the product is reserved for sale only through pharmacies.

To bring about a single European market in pharmaceuticals, the European Commission established a "mutual recognition procedure" for the entry of drugs into the European market, which became effective January 1, 1988. European regulation of pharmaceuticals — which includes both medications and cosmetics — is, however, still in its early stages.

The European Union has established a harmonized approval process for medications, and it has also established a common European Commission application procedure. The soon-to-be-passed European Directive on Generic Medicines will further harmonize the European market.

The following are products that can only be sold through French pharmacies:

- Medicines, by their composition, use or presentation (with the exception of "liberalized medications").
- Body-hygiene products and dietary items that contain chemical or biological ingredients that are not foodstuffs and that contain special dietary therapy agents.
- Nicotine suppressors as well as other smoking-cessation products.
- Bandages and all ligature and surgical suture material, catgut, natural and synthetic hairs, linen and collagen straps or synthetic or polyester adhesives.
- Certain dermatopharmaceutical products.
- Insecticides and acaricides for human use.
- Products for contact lens application and maintenance (subject to specific authorization that is distinct from the procedure for introduction of pharmaceutical products).

Indeed, the proposed generic medicines directive, with its broader definition of "eutrogenic" products and its unified procedure, will no doubt result in a great increase in the number and diversity of generics in Europe. However, that directive only governs generic medicines; it still has to be passed and implemented in the member states.

National law thus remains very relevant. Indeed, in most of the European Union member states the very scope of pharmacists' control over the sale of medicines and other products in drug stores and pharmacies remains an issue of national law.

Certain European countries, including Germany and Belgium, have established a legislative definition of medicines, whereas others, such as Italy and the United Kingdom, have not.<sup>1</sup> and European law leaves it to the member states to determine rules regarding the sale of pharmaceutical products within national borders. European and national courts have repeatedly held that national legislation reserving a product for sale within pharmacies does not constitute a violation of common market principles.

When an American manufacturer of medicines or cosmetics attempts to introduce a product into one of the European Union member states its classification is determined by substantive national rules. Thus, the traditions or legislative whims of a country like France might cause a product to be classified as a "medicine" that may only be sold in a pharmacy but may not require a

medical prescription.

Indeed, although the Directive on Classification (92/26/EEC) of March 1992 established that medicines should be classified as either prescription or nonprescription, when products are introduced to individual countries — as opposed to throughout the European Union — differences may arise in the regulation of individual medications.

To the distress of some,<sup>2</sup> a product may face an easier path to approval when it is introduced in one member nation as opposed to another. If a pharmaceutical company wants to market a drug in more than one member country the first nation to approve the drug becomes known as the "reference member state."

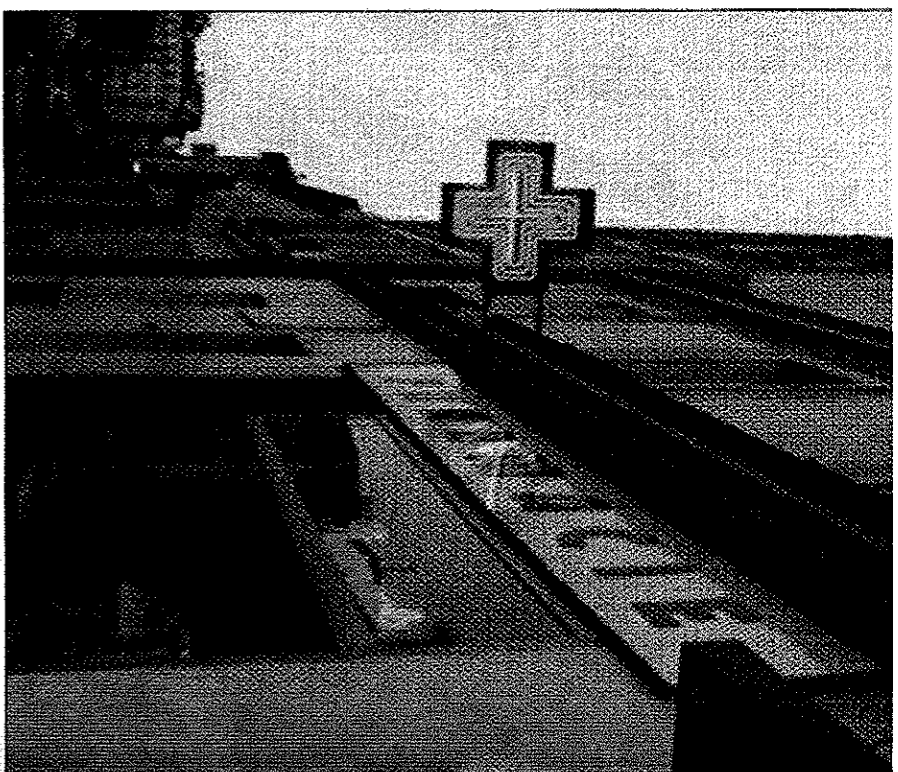
Some claim that this lack of harmonization results in a risk to the public health, allowing entry of products into the European market by more liberal pathways, such as through England.<sup>3</sup> However, states Dagmar Roth-Behrend, a member of the European Parliament, "there are apparent deficits in the functioning of the mutual-recognition procedure, since some member states sometimes do not accept a market authorization from others."<sup>4</sup>

## Entry of a product into the French market

According to the French Code of Public Health, for a company to validly manufacture, prepare or import pharmaceutical products in France, that entity must declare its existence to the Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), which is an administrative agency operating under the aegis of the French Ministry of Health. In addition, the entry of cosmetics and medicinal products into the French market requires that information on their composition be provided to the French anti-poison authority. This information is certified by the manufacturer, its representative, the distributor of the products or the agent responsible for their initial entry from a non-European Union country.

This entity must comply with certain criteria, such as scientific qualifications, which are established by diplomas and academic titles. When approval has already been obtained in another European Union country, the distributor or commercial agent in that member state can make this application, in light of European mutual-recognition legislation.

Both cosmetics and medicinal products are subject to application and expert review before the AFSSAPS. Indeed, cosmetics are deemed to be health products (produits de santé) and are subject to the regulations of the French Public Health Code. However, medicines (*médicaments*) are subject to the pharmacy monopoly, meaning that they may only be sold in pharmacies.



## The pharmacy monopoly in France

In France when a product is deemed to be a medicine under the governing Article L. 512 of the French Code of Public Health it falls within the monopoly pharmaceutical, and thus may only be sold in an establishment where a licensed pharmacist is on duty. Such sales must be made directly between the pharmacy and the consumer — no intermediary is permitted.

French legislation expressly prohibits sales through such intermediaries as wholesale groups, supermarkets or any business that is owned or administered by an individual who does not have a pharmacist's diploma. Furthermore, certain other products not specifically falling under the definition of medication are also subject to the pharmacy monopoly and may therefore not be sold outside of a pharmacy. A nonexhaustive summary of such products appears in the box on this page.

A product may be deemed to be a medicine in France according to its presentation, its function or its composition. Regarding presentation, when a product (such as a plant) normally does not fall under the compositional definition of a medicine is marketed in the form of gelscaps or pills it may still be deemed to fall under the pharmacy monopoly. While cosmetics fall under the definition of pharmaceutical products and require the above-mentioned approval, once such approval is obtained their sale is not subject to the pharmacy monopoly and may be sold in any outlet.

Some stores, called "parapharmacies" in France, specialize in cosmetic products and other nonmedicinal items. Parapharmacies are managed by a pharmacist but do not require a pharmacist to be on duty.

Whereas in other countries of Europe both pharmacies and authorized druggists have the authority to sell over-the-counter

medicines, in Belgium and France such items are only available in pharmacies. Legislation on homeopathic treatments also may differ from country to country.

In France herbal treatments that are not subject to conditioning may be sold by licensed herbalists, who may sell all plant substances that are listed in a pharmacopoea and not classified poisonous substances. Furthermore, a certain number of plants have been exempted from the pharmacy monopoly and are sold without restriction.

Only certain plant substances, approved by decree, can be mixed together in one product. Veterinarians and opticians also benefit from certain exemptions from the pharmacy monopoly.

It remains to be seen to what degree national pharmaceutical regulations will remain relevant in light of the harmonizing trend of generic products. But national resistance to the implementation of European market rules can be expected, especially from France.

## Notes

<sup>1</sup> Droit pharmaceutique, Editions Leduc, Section 4, page 7.

<sup>2</sup> For example, "En pratique, la politique actuelle du médicament tourne le dos à santé publique," *La Revue Prescrire*, June 2002/Tome 22, No. 229.

<sup>3</sup> John Abraham, "A license to print money?," *Health Matters*, No. 43, Winter 2000/01.

<sup>4</sup> Dagmar Roth-Behrendt, speaking at, and as reprinted in, the World Self-Medication Industry (WSMI) 13th General Assembly, Health Policy in Europe, page 87.1.

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## Le Monopole Pharmaceutique Français

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• Products whose purpose is to obtain a medical diagnostic, "paper tests" or pregnancy tests (there is considerable division among French courts as to whether they belong in the pharmaceutical monopoly).

- Radiopharmaceutical items.
- Instrument cases as well as generators.
- Poisonous plants, and "medicinal plants" (with the exception of "liberalized" plants).
- The retail sale of certain essential oils, expressly specified by regulations, are reserved to pharmacies, including those essences made of absinth, armoise, cedar, hyssop, sauge, tannaisie, thuya. However, essential oils for cosmetic, cleaning or food use are excluded.
- Dietetic products and certain food products for infants.
- Veterinary products are subject to similar regulation.
- Contraceptive substances.
- Abortive devices and objects (nonetheless rarely available in pharmacies, reserved most often to medico-surgical suppliers).
- Syringes and needles.