Romania

Contributing firm
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Selection, clearance and registration

Regulatory bodies and requirements

The National Drug Agency (ANM), a public institution under the control of the Ministry of Health, is the body responsible for the authorization of drug production, import, registration and distribution. The registration process with the ANM takes on average between 12 and 18 months. However, this is reduced (to around three months) for drugs having registration certificates from the European Medicine Evaluation Agency. Drugs must be re-registered every five years and this process can take up to 10 months. The procedure for drug registration is now in line with EU standards.

The Control Department within the ANM is responsible for:

- monitoring drug quality;
- inspecting production facilities; and
- issuing certificates of Good Manufacturing Practice (GMP).

The GMP certificate must be renewed every other year. The law initially required all domestic producers to be GMP compliant by the end of 2000, but this proved to be totally unrealistic.

Every year, the ANM draws up a list of drugs that can be issued through medical prescription in Romania, specifying, as the case may be, the classification category. The updated list is submitted annually to the European Commission or directly to the other EU member states. The ANM also classifies each year the drugs authorized to be sold in Romania, stating the release classification for each drug.

The role of the ANM includes an obligation to assess whether the proposed invented name for a drug poses public health problems or a risk to safety. Even when an invented name for a drug is registered in Romania or in other EU member states, it is public safety considerations that determine whether the proposed name can be used for the drug in question.

According to the Romanian legislation in force, pharmaceutical goods for human use can be sold only after a market release authorization has been issued by the ANM. The authorization is issued for pharmaceutical goods for human use that fulfil the quality, safety and efficacy requirements set forth in the current provisions.

The applicant for a market release authorization must be:

- a Romanian legal person with an operation authorization issued by the Ministry of Health or;
- a foreign manufacturer authorized according to the law in its country of origin, with a subsidiary in Romania or a Romanian legal person duly delegated by the manufacturer. Such legal person must employ professional personnel (eg, medical practitioners). The designation of a representative does not release the owner from its legal liability according to Article 700(4) of the Healthcare Reform Law (95/2006).

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Confusion with INNs

Drugs without a name will not be authorized for release on the market by the ANM. The commercial name (marked with the letter 'R') is chosen by the company or factory that manufactures the drug and should be an invented name. This name refers to the drug's final form, which contains the active ingredient and additional substances.

The Market Release Authorization Directorate (DAPP) of the ANM assesses names to ensure that they do not lead to a risk of confusion with international non-proprietary names (INNs) or, if such a name does not exist, the usual non-proprietary or scientific name.

The DAPP will also determine the likelihood of confusion in relation to:

- certain applications seeking a variation;
- transfers of market release authorizations;
- changes in design or to drug labels; and
- requests, where the drug is for human use but is not intended to be released directly to the patient, for an exception from the obligation to:
  - include certain information on the label and in the leaflet; or
  - print the leaflet in Romanian.

Should the DAPP determine that there is a likelihood of confusion with an INN or another non-proprietary name, it shall file with the ANM a notice requesting an amendment to the name proposed in the authorization application. However, the DAPP does not consider whether names are in conflict with prior IP rights. This area is controlled by the State Office for Inventions and Trademarks and the courts.

Non-traditional trademarks

Trademarks are now viewed as highly valuable in the pharmaceutical industry and therefore require protection. Law 84/1998 on trademarks and geographical indications sets out four basic requirements for protection as a trademark: the sign must be:

- capable of graphical representation;
- distinctive;
- legal; and
- available.

In addition to word marks and logos relating to the name of a pharmaceutical product, manufacturers may seek to protect other aspects, such as the shape of a particular tablet or product packaging. Article 3 of Law 84/1998 expressly provides that the following types of sign may constitute trademarks:

- three-dimensional forms;
- the form of the product;
- the form of the packaging;
- other forms; and
- any combination of the above forms with other elements – namely, letters numbers, words, verbal expressions, figurative elements and/or colours.

In the case of three-dimensional trademarks, Article 5(e) provides that the form should not:

- be imposed by the nature of the product;
- be necessary to obtain a technical result;
- give substantial value to the product.

Where a three-dimensional mark is associated with other elements (eg, words and figurative elements), it will be examined as a combination mark. From a practical point of view, if the verbal elements lack distinctiveness the sign will be assessed as a simple three-dimensional trademark.

Parallel imports and repackaging

The Romanian Association of International Medicine Manufacturers (ARPIM) is a professional organization that gathers together the Romanian subsidiaries of the main international pharmaceutical companies. It is affiliated with the European Federation of Pharmaceutical Industries and Associations, an organization that promotes the interests of international pharmaceutical companies.

In a bid to thwart the efforts of parallel importers, the Ministry of Health and the ARPIM have recalculated the country entry costs, which include the Carriage and Insurance Paid to (ie, CIP) price, for drugs. The new calculation, which will come into effect in 2009, takes into account the average of the lowest prices in 12 EU countries and applies a 5% reduction so that the foreign currency price decreases by 6.82% for all drugs on all subsidization lists. The ARPIM hopes that this new method of calculating the price of imported drugs will prevent parallel importers that, completely legally, exploit the differences between national drug pricing policies. However, despite the ARPIM's and Ministry of Health's concerns, parallel imports have not yet posed a significant problem in Romania.

Any attempts to distort the market are outlawed by competition law, which prohibits concerted practices that aim at or result in the reduction, prevention or damage of competition on the Romanian market. These include decisions which aim to limit or control distribution. In addition, any block on the pharmaceutical market limits the access of drug producers in other EU member states to enter the Romanian market, thus creating the risk of affecting inter-Community trade in pharmaceutical goods.

Anti-counterfeiting and enforcement

Counterfeit drugs are sold on the Internet in increasingly greater numbers in all EU countries. These pills pose a genuine threat to the health of those who use them.

According to pharmacists in Romania, official channels of distribution for pharmaceutical products have not been disrupted by counterfeit goods. They point to the fact that experienced professionals such as pharmacists are fully aware of the security elements used on the packaging of pharmaceutical goods and the standards that must be observed. Reliable suppliers cannot afford to damage their reputation by selling counterfeits. However, counterfeits may enter the supply chain of shops trading in natural pharmaceutical goods because these sellers are not skilled in spotting the differences between original drugs and counterfeits. While such occurrences are often inadvertent, things change in the case of goods sold on the black market, online or through classified advertisements.

The Romanian National Consumer Protection Authority is dedicated to stemming the trade in counterfeit goods and a special unit of the police also handles such issues. Under the current law, the police can intervene to prevent trademark counterfeiting only when the rightful owner of the mark makes a complaint. Further, customs authorities have no power to take action in trademark counterfeiting cases without instruction from a rights holder. Customs will act on the basis of either an intervention request filed with the General Directorate of Customs or a public action. In both cases the customs authorities must have reasonable suspicion of infringement and they can detain goods only where there is reasonable suspicion that the goods are counterfeit.

Advertising

Law 148/2000 (*Official Gazette* Part I 359/2000) sets out the legal framework governing advertising in Romania. According to Article 7, "advertising is allowed only for pharmaceutical goods issued without medical prescription for which the advertising materials shall be approved by the ... [ANM]".

Pursuant to this law, the Ministry of Health and the ANM have drawn up regulations regarding advertising for pharmaceutical goods for human use, which are included in Ministry of Health Ordinance 263 of March 25 2003. The regulations define 'advertising for pharmaceutical goods' as including the promotion of any kind of information by direct contact (eg, door-to-door sales), as well as any form of promotion intended to stimulate the prescription, distribution, sale or consumption of pharmaceutical goods.

In particular, the regulations cover the following types of activity:

- Advertising for drugs aimed at the general public or those qualified to prescribe or distribute drugs;
- Visits by representatives from pharmaceutical companies to those qualified to prescribe drugs;
- Distribution of samples;
- Stimulating the prescription and distribution of drugs by offering, promising or giving certain benefits, whether financial or in kind, except when such benefits are of symbolic value; and
- Sponsorship of promotional meetings and scientific congresses attended by qualified people.

The regulations make clear that advertising for pharmaceuticals should encourage the rational use of the drug by presenting it in an objective manner and without exaggerating its properties. In addition, the advertising must not be misleading.

Advertising intended for the general public is prohibited for drugs that:

- are issued solely on the basis of medical prescription;
- contain substances defined as narcotic or psychotropic; and
- are prescribed and issued under the health insurance system.

The distribution to the general public of pharmaceuticals for advertising purposes is also prohibited.

Generic substitution

Generic drugs play a key role in the Romanian prescription pharmaceuticals market. Romania has traditionally had a strong generic drug manufacturing system. Price is also an extremely important consideration, especially on a market where the national health insurance system is chronically underfunded.

Strengthening the position of generics yet further, in 2005 Romania implemented measures requiring medical practitioners to prescribe medicines using the relevant INN instead of a brand name. Such measures are practised and promoted at EU level.

In addition, pharmacies are obliged to issue the cheapest available drug that corresponds to the prescription. This keeps the cost to the patient as low as possible. Such obligations are welcome at this time since the Romanian health system is still a long way behind many other EU member states in terms of finance and organization. Any obligation to implement a measure leading to an increase in the prescription of expensive original drugs would have a negative impact on patients and would put Romania even further behind other EU models.

Online issues

Online trade in pharmaceutical goods is a new challenge for traditional chains of pharmacies in Romania. As yet, only a few such chains have an internet presence and expansion is severely limited by legislative provisions. At present, the legislation in force prohibits the sale of prescription drugs online. Such pharmaceuticals must be handed directly to the patient by the pharmacist in an authorized location. Despite these strict controls, online pharmacies are starting to threaten the market strength of traditional pharmacies.

The online pharmacies market took off in Romania only around two years ago. Now business is booming with ever-increasing demand, especially in large cities. As this market continues to expand, the authorities will have to implement further controls and enforcement mechanisms to ensure that counterfeit products do not enter the supply chain. WTR

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