

Romania

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Selection, clearance, registration

Regulatory bodies and requirements

Prior to placing a medicine on the Romanian market, a marketing authorisation must be obtained either by following the national procedure or in accordance with the EU centralised procedure. The state authority responsible for issuing the marketing authorisations is the National Medicine and Medical Devices Agency (NMMDA).

Medicines that are generics of an innovative medicine will be authorised following a special procedure. In accordance with the relevant provisions of the law, a generic medicine can be authorised after the innovative medicine has been authorised in Romania or the European Union for at least eight years and may be marketed only after a 10-year period has elapsed after the authorisation for the innovative product was granted.

The authorisation procedure for a generic medicine is simpler and thus usually considerably shorter than the authorisation procedure for innovative medicines. The applicant for a marketing authorisation for a generic medicine is not required to supply the NMMDA with the results of clinical trials. However, it must provide the results of bioequivalence studies that show that the generic has the same effects as the innovative medicine.

The law provides for a 210-day period for the NMMDA to take all necessary measures to examine and grant a marketing authorisation. However, this time limit is a recommendation, not an obligation. Consequently, it is rarely respected and three years are more likely to elapse, especially in the case of innovative drugs, before an authorisation is granted.

The marketing authorisation is valid for a period of five years and can be renewed after the initial five-year period. The renewal application must be filed six months prior to the expiration date. In case the NMMDA grants the renewal, this second

authorisation is valid indefinitely, unless the authority holds otherwise.

The holder of the marketing authorisation must start the commercialisation of the medicine within three years of the granting of authorisation. If the commercialisation of the products does not start within the prescribed period, the authorisation is automatically cancelled.

The law also provides for special authorisation procedures for homeopathic medicines and medicines based on plants.

After a marketing authorisation is obtained, in order to be able to start the commercialisation of a product a decision regarding the price must also be obtained from the Ministry of Health. Such a decision is issued within 90 days of the application date.

Confusion with INNs

One of the conditions that the NMMDA will verify in the authorisation process pertains to the name of the medicine. Under the law an applicant may choose between:

- an invented name, which must not

create any confusion with a common name; and

- a common name or a scientific name, together with the trademark or trade name of the holder of the marketing authorisation.

The 'common name' is defined by law as the international non-proprietary name (INN) recommended by the World Health Organisation, or, if none exists, the usual common name.

In case the NMDA considers that the name selected by the applicant is liable to create confusion with a common name (as defined above), the applicant will be notified and requested to select another name that fulfils the authorisation conditions.

However, the NMDA will not clear the selected name as far as prior IP rights are concerned. Therefore, obtaining a marketing authorisation does not guarantee that the name selected for the product is cleared for use in Romania. This is why most applicants also conduct availability searches in order to ensure that the selected product name will be available for use once the marketing authorisation is granted.

In case the marketing authorisation is granted for a product name that cannot subsequently be used due to a conflict with a prior IP right, the holder of the marketing authorisation will have to notify the NMDA and request modification of the authorisation. This will result in further delay for the commercialisation of the product.

Some manufacturers, in particular those of generic drugs, choose the second option – namely, they select the common name or the scientific name together with the trademark or trade name of the holder of the marketing authorisation.

Non-traditional trademarks

Trademarks are crucial for manufacturers of pharmaceutical products, especially over-the-counter medicines. This is because direct communication with the patient is decisive. Existing regulations impose no restrictions on pharmaceutical manufacturers with regard to any attempts to influence purchase decisions.

Although Romanian trademark law provides for the possibility to register a variety of non-traditional trademarks (eg, three-dimensional marks, colours, holograms, sound marks), the vast majority of pharmaceutical trademarks are traditional marks (mostly word marks and combination marks). Non-traditional trademarks are still rare and the author

believes that this will remain the case in the future because of the restrictions imposed on advertising.

There are some notable exceptions of three-dimensional trademarks that have acquired a reputation over the years and have proven successful. However, this is mostly due to factors outside the IP field.

Parallel imports and repackaging

The conditions required for the parallel importation of medicines in Romania are set forth in Procedure 2/2008 issued by the Ministry of Health.

Any person that intends to parallel import medicines in Romania has to apply for and obtain an authorisation from the NMDA. The parallel-imported medicines cannot be placed on the market before the authorisation is granted.

'Parallel import' is defined as the introduction onto the Romanian market of a product for which a marketing authorisation has been granted, using other distribution channels than those accepted by the holder of the marketing authorisation. Minor differences between the parallel-imported medicine and the medicine distributed directly by the holder of the marketing authorisation are accepted, as long as the therapeutic effect of the two medicines is the same.

The NMDA will issue the marketing authorisation for parallel-imported medicines within 45 days of the application date. In case there is any irregularity with the application, the NMDA will notify the applicant within 30 days.

It is clear from the above that the authorisation for parallel-imported products is an expedited one, with a minimum of requirements and formalities to be undertaken.

However, the parallel importer is also required to obtain a wholesaler authorisation. Concurrently, the parallel importer is required to secure manufacturing authorisations as well if it intends to modify the label or the packaging. Consequently, the parallel importer must obey the good practice rules established for the production and distribution of the medicines at issue.

The authorisation is valid for a period of five years and can be renewed for another five years. A separate authorisation is required for every country of origin of the parallel-imported medicine.

The procedure established by the Ministry of Health concerns exclusively the authorisation to parallel import medicines. The procedure states that all matters related

to IP rights are to be the sole responsibility of the parallel importer.

The apparent conflict between a parallel-importation operation and the trademark rights owned by the manufacturer of the product has been addressed by EU jurisprudence, which is applicable in Romania.

Therefore, the proprietor of the trademark may not oppose the repackaging of a medicinal product when the following conditions have been met:

- The use of the trademark right by the owner contributes to the artificial partitioning of the internal market;
- The repackaging does not adversely affect the original condition of the product;
- The new packaging states by whom the product has been manufactured and repackaged;
- The presentation of the repackaged product is not such as to damage the reputation of the trademark and of its proprietor; and
- The proprietor of the trademark receives written notice of the repackaging before the new product is put on sale.

The parallel importer is required to notify the holder of the marketing authorisation in advance of the actual commercialisation of the product and provide it with all necessary information in order for the holder of the marketing authorisation to decide whether its IP rights will be infringed by the parallel importation.

Since the adoption of the procedure, the NMDA has issued fewer than 40 parallel import authorisations, for only two companies. Most of the authorisations have been issued for over-the-counter medicines, with some of the most famous brands present on the list.

However, parallel imports do not seem to be a problem for marketing authorisation holders in Romania. This is probably due to the pricing policy imposed by the Ministry of Health, which keeps prices down compared to those in other EU countries and therefore makes parallel imports less attractive (a fact that is apparent from the list of only three or four countries from which parallel-imported medicines originate).

Anti-counterfeiting and enforcement

The issue of counterfeit medicines is taken very seriously by the Romanian authorities. All necessary measures, including specialised websites where notices regarding counterfeit medicines are periodically

posted, have been taken in order to limit the negative impact of such products on the population.

Romanian law is also harmonised with the EU provisions regarding the measures put at the disposal of industrial property owners for the enforcement of their rights. One of the most valued and effective measures is the possibility to register rights with the customs authorities in accordance with the EU Customs Regulation (1383/2003).

Fortunately, cases of counterfeit medicines in Romania have been few and far between. With the exception of small-scale shipments of medicines that have occasionally been seized by the authorities (and which have proven to be harmless to the public), the Romanian market appears to be quite safe.

The distribution chain from manufacturer/importer to the pharmacies is well controlled and regulated and, therefore, the presence of counterfeit products in pharmacies is an unlikely event.

The only chink in the system's armour is the presence of stores selling natural remedies or food supplements which fall outside the regulatory scope of the legislation regarding manufacturing, marketing and distribution authorisations. Therefore, on a number of occasions food supplements have been marketed as an alternative to a medicine, sometimes using the trademark of the medicine for that purpose.

At this point in time, the online commercialisation of pharmaceutical products is the main counterfeiting threat. Although this method of marketing medicines has not been very successful in Romania, it still represents the best opportunity for commercialising counterfeit pharmaceutical products to Romanian consumers.

Advertising

The relevant Romanian legislation institutes a very strict regulatory framework for advertising medicines.

Any kind of advertising for a medicine that has not been granted a marketing authorisation is forbidden. When authorised, advertising of pharmaceuticals must encourage the rational consumption of medicines without exaggerating the properties of the beneficial effects of the medicine; it must not be deceiving.

All advertising for prescription-based medicines is forbidden. Also forbidden is advertising for medicines that contain narcotic or hallucinogenic substances.

(However, advertising for vaccination campaigns is permitted.) The promotional distribution of medicines directly to consumers is strictly forbidden.

The NMMDA recently published a guide for the evaluation of advertising for medicines for human use.

According to this guide, all advertising materials for over-the-counter medicines and educational materials aimed at consumers must be submitted for approval by the holder of the marketing authorisation to the NMMDA. Advertising materials aimed at professionals will be evaluated by the NMMDA after being put on the market, at random or following a complaint. To this end, all advertising materials (in electronic or printed form) must be retained by the marketing authorisation holder for a period of three years.

Comparative advertising (including for generics) is forbidden for all materials destined for consumers. However, this is permitted in the materials destined for medical professionals under some conditions.

The guide represents the first Romanian attempt to regulate advertising on the Internet. The guide requires that any website that contains advertising for medicines comply with a number of rules, such as the clear identification of:

- the identity of the person operating the site and its physical address;
- the source of the information;
- the target public; and
- the purpose and objective of the website.

All information on the website must be periodically submitted to the NMMDA for review and authorisation. Such a site may contain non-promotional materials aimed at patients, non-promotional educational materials related to health in general, treatment and screening methods. All of these materials may relate to a specific product, as long as the information is balanced and accurate.

Although the NMMDA's efforts to regulate online advertising are to be appreciated, one cannot help but notice that the wording of the guide is non-exhaustive and thus can easily be interpreted to the advantage of the advertiser. In addition, enforcing the guide's recommendations is nearly impossible.

Generic substitution

The Romanian healthcare system has been struggling to cope with rising costs for the better part of the past 20 years.

In order to cut costs to an acceptable level, a number of measures have been adopted. The prices of medicines on the Romanian market are strictly regulated and are aimed at keeping them at the lowest possible level compared to other EU countries. However, this policy has had the unwanted result of some high-priced medicines being withdrawn by their manufacturers from the Romanian market.

Another measure, which has been in place since 2005, is the obligation for medical practitioners to use INNs rather than brand names on prescriptions, which are subsidised by the national healthcare system. This is another measure aimed at cutting costs for the healthcare system while providing patients with the most cost-effective option. Practically, the least expensive medicine from a particular pharmaceutical group attracts the highest subsidy, while patients who prefer a branded, more expensive medicine must cover most of the price themselves.

Online issues

According to the relevant legislation, the commercialisation of medicines on the Romanian market is done exclusively through pharmacies, local distribution offices and drugstores.

Therefore, although not specifically mentioned by the law, the commercialisation of medicines online is forbidden. A number of online pharmacies nevertheless exist, although their market share is close to nil.

This is most likely going to change in the near future, in light of Directive 2011/62/EU, which provides for the existence of online pharmacies. These e-pharmacies will display a common logo intended to guarantee the origin of the products sold. Since EU member states have two years to implement the directive, it is likely that the national legislation will be modified in the near future to accommodate this new method for marketing medicines. [WTR](#)

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Dragosh Marginean has been working in the IP field since 2000. He graduated from law school in 2002 and in 2003 he co-founded the fastest-growing IP firm in Romania, Ratza & ratza, which provides a full range of IP prosecution and litigation services. While Mr Marginean is primarily involved in trademark and patent litigation work, he also dedicates time to law reforms, as well as writing articles on various IP topics.