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Information about drug registration in Romania

According to Romanians laws, medicinal products for human use can be marketed only after the granting of Marketing Authorization by the National Medicines Agency. The Marketing Authorization is granted for medicinal products for human use, which fulfill the quality, safety and efficacy conditions mentioned in the present regulations.

The National Medicines Agency authorizes for marketing the following medicinal products for human use:

- products which contain chemical substances;
- radiopharmaceutical products;
- biological products;
- phytotherapeutic products;
- homeopathic products;
- products obtained through biotechnology.

The applicant for a Marketing Authorization should be Romanian manufacturer, juridical person owning functioning authorization issued by the Ministry of Health and Family or foreign manufacturer authorized in accordance with the legislation from the country of origin, with representative office in Romania or Romanian juridical person empowered by the manufacturer, with specialized personnel employed (physicians or pharmacists).

In order to start the procedure for marketing authorization of a medicinal product for human use, the applicant submits to the National Medicines Agency an application. At the application it should be annexed the application's supporting documentation in accordance with the **legal documents**

Depending on the product type, the following types of applications can exist:

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1. Applications based on complete own documentation = “independent” applications (for new chemical entities); the supporting documentation of an application for a new chemical entity should contain:

- a)** name and permanent address of the applicant and manufacturer if applicable;
- b)** trade name of the medicinal product;
- c)** qualitative and quantitative characteristics of all the constituents of the medicinal product named in usual terminology, but excluding empirical chemical formulae, with mention the international non-proprietary name (INN) recommended by World Health Organization (WHO), if any;
- d)** description of manufacturing method;
- e)** therapeutic indications, contra-indications and adverse reactions;
- f)** posology, pharmaceutical form, method and route of administration and expected shelf-life;
- g)** if applicable, any precautionary and safety measures which should be taken for storage of the medicinal product, its administration in patients and for the disposal of waste products, together with an indication of any potential risks presented by the medicinal products for environment;
- h)** description of control methods used by the manufacturer (qualitative and quantitative analysis of the constituents and the finished product, special tests e.g. sterility tests, tests for the presence of pyrogenic substances, the presence of heavy metals, stability tests, biological and toxicity tests, controls carried out at an intermediate stage of the manufacturing process);
- i)** results of:
 - physico-chemical, biological or microbiological tests;
 - toxicological and pharmacological tests;
 - clinical tests.
- j)** a summary of Product Characteristics, one or more specimens or mock-ups of secondary and primary packaging of the medicinal product, together with patient leaflet;
- k)** documents showing that the manufacturer is authorized to manufacture the medicinal product;

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I) copies of any Marketing Authorization granted by other countries together with the list of countries where the product is under authorization procedure; copies of the summary of product characteristics proposed by the applicant or approved by the competent authorities from other countries; details of any decision to refuse authorization and the reasons for such a decision.

This information should be updated on a regular basis.

In addition to this requirements, the application for marketing authorization for a radionuclide generator should also contain the following information:

- a general description of the system, together with a detailed description of the system components, which may affect the composition or quality of the daughter-radionuclide preparation;

- qualitative and quantitative characteristics of the eluate or sublimate.

2. Applications for marketing authorization for which own toxicological, pharmacological and clinical studies are not required.

a) the applicant will not be required to submit the results of toxicological and pharmacological tests or the results of own clinical studies if he can demonstrate that:

(i) either the medicinal product is essentially similar to a medicinal product already authorized in Romania and the marketing authorization holder of reference product consents that for the purpose of the respective product examination to refer to its product toxicological, pharmacological and/or clinical documentation (application with reduced documentation based on “informed consent”);

(ii) or the medicinal product constituent(s) have a well established medicinal use, with recognized efficacy and an acceptable safety level, with the support of detailed scientific bibliography (“bibliographic” application);

(iii) or the medicinal product is essentially similar (proved through bioequivalence studies, where applicable) to a medicinal product which was authorized in Romania based on a complete dossier (original product/ reference product for Romania) and which is no longer covered by patent protection (application with reduced documentation based on the proof of bioequivalence

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where applicable, with the original / reference product = application for generic products).

However, where the medicinal product is intended for a different therapeutic indication from that of the other medicinal products available on the market or is to be administered by different routes or in different doses, the results of appropriate toxicological and pharmacological tests and /or appropriate clinical trials must be provided.

b) In the case of new medicinal products which contains known constituents not hitherto used in combination for therapeutical purposes, the results of toxicological and pharmacological tests and clinical trials relating to that combination must be provided without being necessary to present data regarding each individual constituent.

The authorization application will be accompanied by two samples of the finished product presented in the packaging that follows to be marketed or in mock-ups of the packaging (with the obligation to present the final packaging to the National Medicines Agency after producing the first production batch after the granting of the Marketing Authorization).

In the cases mentioned in the decision no. 24/2002 of the National Medicines Agency Scientific Council, where it is necessary the performance of the laboratory control in the frame of the authorization procedure, the authorization application will be accompanied by the following materials, in the view of laboratory verifications: finished product samples presented in the packaging that follows to be placed on the market or in the packaging mock-up (with the obligation to present to the National Medicines Agency the final packaging after producing the first production batch), in sufficient quantities to allow the verification of all quality parameters from the quality specification and in accordance with the methodology presented in the chemical, pharmaceutical and biological documentation, reference substances, supplemental reagents (where appropriate), degradation products (where appropriate), impurities (where appropriate).

If the medicinal product is presented in more packaging sizes, the control laboratory will be done on the smallest packaging size product; for the other packaging sizes, there are required only 2 samples.

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For each different pharmaceutical form and strength of a medicinal product presented under the same trade name, separate application requests are submitted.

The documentation should be submitted in one copy, with the exception of chemical, pharmaceutical and biological documentation that will be submitted in 2 copies.

The documentation should be strictly presented in the order stipulated in the Section D, which is part of the present regulations.

The documentation for imported medicinal products can be presented in Romanian, English or French.

*If you would like to **register a drug in Romania** you can ask GTS Solution to do that for you.*

With our long experience with registering drugs in Romania, we will help you get your product registered in the shortest time and with no effort from your part.

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