

## HERBAL DRUGS AND TRADITIONAL HERBAL DRUGS IN THE REPUBLIC OF SERBIA

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According to the Law on Medicines and Medical Devices of the Republic of Serbia, which is harmonized with the European directives on medicines, a substance that is an active component of a medicine can be of plant origin. Herbal medicine - HM and traditional herbal medicine - THM are used for the prevention and treatment of certain diseases and conditions, their initial, mild, but also chronic and recurrent forms.

The guidelines on the pharmaceutical quality of HM and THM insist on a rigorous and detailed definition of plant raw materials, production process, and finished pharmaceutical products. Registration of these types of drugs is done by the Agency for Drugs and Medical Devices of Serbia (ALIMS). During the HM registration process, the Herbal Anatomical Therapeutic Chemical (HATC) system (an integral part of the WHO Drug Global Classification of products and substances) is applied. For now, the number of registered HMs and THMs in Serbia is modest in comparison to their number in most EU member states. ALIMS controls the content of the patient information leaflet for the medicine: all data on indications, dosage, contraindications, precautions, adverse effects, and interactions. Therefore, the application of registered HMs and THMs constitutes a modern phytotherapeutic approach and the safest way to use herbal medicinal substances and preparations.

In addition to medicinal, there are other categories of herbal products on the market (herbal supplements, herbal teas...) that are not intended for therapy and treatment. Dietary products are regulated by other laws and regulations, and after entry in the Register of Dietary Products of the Ministry of Health, they can be realized in the Serbian market.

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