

## PARADIGM OF ADAPTOGENS

© **Kovaleva M.A., Makarova M.N., Makarov V.G.**

*Saint-Petersburg Institute of Pharmacy, Leningrad region, Vsevolozhsky district, 188663, Kuzmolovo P 245, Russia*

At the present time, the problem of maladaptation of human body to the environmental conditions, food components, physical and mental workloads acquires specific relevance and actually vital necessity. Destabilization of human body to all adverse environmental factors is determined by functioning of almost all organs. According to this, natural adaptogens are optimal solution, what increases smoothly physiologically the safety capacities of a body. The history of their use for medical and general tonic purposes counts several thousand years. Nowadays the mass media has broadly deformed the true conception of adaptogens usage, posing them as panacea. The adaptogens, which were produced in mass production as dietary supplement, exhibited low pharmacological activity connected with uncontrolled use. The patients, resorting to self-medication, didn't consider their life style, social factors, job category, kind of nutrition and personal attributes.

So far, the development of new adaptogenic substances research concept is important subject, what will permit to take into account basic personal characteristics

(psychological type, chronotype), gender identity, activity, etc. In our laboratory we took such a shot for developing of two types of adaptogenes: Adaptogen morning (extracts roots of *Eleutherococcus senticosus* Rupr. et Maxim., rhizomes of *Leuzea carthamoides* DC., leaves of *Bergenia crassifolia* L., fruits of *Rosa hips*, fruits of *Crataegus sanguinea* Pall. and fruits of *Coriandrum sativum* L.) and Adaptogen evening (extracts *Rhodiola rosea* L., *Melissa officinalis* L., *Tilia cordata* Mill. et *Tilia platyphyllos* Scop., *Thymus serpyllum* L., *Epilobium angustifolium* L., *Leonurus cardiaca* L., *Melilotus officinalis* Pall., *Crataegi*, *Humulus lupulus* L.), for body response correction to negative factors. The in vivo studies were done on male and female mice of C57Bl/6 and Balb/C lines which allowed to take into account sex and psychological type differences in response to stress. The test of Jouvett, Portsol test, tail-suspension test (TST), light/dark box test were used as stress models. Based on our findings, Adaptogen evening can be suggested for women of any psychological type. Adaptogen morning is recommended for both men and women of phlegmatic and melancholic psychological types.

## ISSUES RELEVANT TO STANDARDIZATION OF INFORMATION ON HERBAL MEDICINAL PRODUCTS

© **Kovaleva E.M., Lyakina M.N., Nikolaeva O.B., Shelestova V.V.**

*Federal State Budgetary Institution "Scientific Center For Expert Evaluation Of Medicinal Products" Of Ministry Of Health Of The Russian Federation, Moscow, Russia*

In the face of constantly increasing nomenclature of medicinal products (MPs) the relevant issue is the issue of the role of the unified information standards of the industry. The main element of information on a medicinal product is its international non-proprietary name (INN) which is introduced by World Health Organization (WHO), though WHO does not establish INN for herbal MPs and mixtures of several substances. The amendments to the Federal Law No.61-FZ "On Circulation of Medicines" introduced by the Federal Law No. 429-FZ require indicating the grouping MP name (in the State Register of MPs, Instruction for use, in labelling, in the registration dossier materials etc.) in case of INN absence. We have put forward the principles of a grouping name formation for herbal MPs that should be compiled based on a Russian generic name of a producing plant and a name of a plant morphological group. Some cases when a specific name of a producing plant is indicated separately in a grouping name are justified.

The principles of a grouping name compilation for multi-component herbal medicinal products are identified, also for those in the function of pharmaceutical substances as parts of composition of tinctures, extracts, and juices.

The attribution of components either to active or to auxiliary ones should be clearly specified in the information on MPs' composition in Marketing Authorization, Instruction for use, MP labelling, and in regulatory documentation. Yet in case of herbal MPs such division is either frequently missing at all or the same component may be defined both, as an active and as an auxiliary one, in the same MP of different manufacturers or in a product of a certain manufacturer authorized in different countries.

The dosage form name constitutes an integral part of a MP information. The Federal State Budgetary Institution "Scientific Center for Expert Evaluation of Medicinal Products" prepared the list of dosage form names