

Section IX
Секція

LEGAL, HUMANITARIAN
AND ECONOMIC ASPECTS

ПРАВОВІ, ГУМАНІТАРНІ
ТА ЕКОНОМІЧНІ АСПЕКТИ

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REGULATORY, MEDICAL AND TECHNICAL ASPECTS
OF CIRCULATION OF MEDICAL DEVICES IN THE FORM
OF SUPPOSITORIES FOR RECTAL AND VAGINAL USAGE

Abstract. Regulatory, medical and technical issues in the classification of medical devices into suppositories for vaginal and rectal use are discussed. Similar features and differences of such health products in the context of legislation for medicines, disinfectants, medical devices, dietary supplements, etc. are considered. It is concluded that modern regulatory practices allow to include suppositories for vaginal and rectal use in the group of medical devices, which is extremely important for the strategy of development and research of such products.

Keywords: medical devices, rectal suppositories, vaginal suppositories, technical file.

A technical file is a set of documentation submitted to a conformity assessment body for a conformity assessment procedure in accordance with the requirements of the relevant technical regulation (TR). The Technical File must contain the documents necessary both for the identification of the product being evaluated and for confirming that the manufacturer has complied with the requirements of the technical regulations for these products. The formation of the Technical File is a responsible task assigned to the party that initiated the procedure of conformity assessment of the TR. The minimum required number of documents included in the Technical File is determined by the Technical Regulations. In this case, the conformity assessment body may require the applicant to provide additional documentation. Before submitting the Technical File to the selected conformity assessment body, it is necessary to make sure that this document not only allows the conformity assessment procedure, but also meets the requirements of the national legislation of the country in which the medical device is placed [1]. Medical device is an any instrument, apparatus, appliance, device, software, material or other product, used alone or in combination with each other, intended by the manufacturer for the purpose of diagnosis, prevention, monitoring, treatment or relief the course of the patient's disease in case of disease, diagnosis, monitoring, treatment, alleviation of the patient's condition in case of injury or disability or their compensation, research, replacement, modification or maintenance of anatomy or physiological process, control of fertilization process and the main expected effect human is not achieved by pharmacological, immunological or metabolic means, but the functioning of which such means can contribute [2].

In this paper, we aim to discuss the classification of medical devices in the form of suppositories for rectal and vaginal use based on the literature and the results of our own research on the example of Pravenor and Prodexin. The medical device Pravenor, rectal suppositories, has the following composition: dwarf palm berry extract (*Serenoa repens*) – 150 mg, lovage root extract (*Levisticum officinale*) – 50 mg, marigold flower extract (*Calendula officinalis*) – 50 mg, excipients:

hard fat. The medical device Prodexin, vaginal suppositories, has the following composition: octenidine dihydrochloride – 2 mg, dexpanthenol – 100 mg, excipients: macrogol 4000, macrogol 400.

To understand the functional properties of the medical device Pravenor we propose to analyze the medical and biological properties of its components and their role in the functioning of the male urogenital system. The composition of dwarf palm berries (*Serenoa repens*) includes the following physiologically active compounds that are essential for the physiological functioning of the prostate: phytosterols (precursors of hormones synthesized in humans), fatty acids (palmitic, linoleic, linolenic), promotes lipase fats, fatty acids, fat-soluble vitamins A, D, E) [3]. The roots of lovage (*Levisticum officinale*) contain many essential oils (terpineol, cineole, acetic, isovaleric and benzoic acids), which have a positive effect on urinary processes. Marigold flowers (*Calendula officinalis*) also contain many essential oils, carotenoids, flavonoids. These compounds play an important role in the recovery of the urinary system [3, 4, 5]. It can be concluded that the herbal substances of the medical device Pravenor are a complex of physiologically active compounds that are important and have a positive effect on the functioning of the male genitourinary system. The main focus in this case is on the support and recovery of the prostate. Critical and crucial is the fact that the previously listed plant components are part of a some of medicines and dietary supplements in various forms of release (use per os). The vast majority of medicines containing dwarf palm extracts or tinctures, lovage and calendula are so-called traditional medicines that were developed and marketed in Ukraine 20 years ago or even earlier. At the present stage of development of regulatory relations in pharmacy, similar products in the form of capsules, tablets and other oral forms are released on the Ukrainian market as dietary supplements, which is more in line with the functional principle of their action – ensuring nutrients for better functioning. This concept is the basis for the preventive action of such products and their assistance in alleviating the course of relevant diseases. Thus, the effect of the medical device Pravenor, rectal suppositories, on the human body cannot be defined as pharmacological or immunological, as well as one that alters metabolism [5]. Therefore, this product can be considered a medical device in the sense of [2].

To understand the functional properties of the medical device Prodexin, vaginal suppositories, we will analyze the composition of its components and generalize about their role in the functioning of the reproductive system of women. Octenidine dihydrochloride is a well-known and researched antiseptic for the treatment of mucous membranes, skin, wound surfaces and etc. This compound reacts with microbial wall and membrane components. This interaction leads to dysfunction of the microbial cell. The mechanism of antimicrobial action includes a number of molecular mechanisms, which include increasing the permeability of the cell membrane of microorganisms to potassium ions. Octenidine dihydrochloride has been shown not to be absorbed in the human gastrointestinal tract or through the skin or mucous membranes, which is critical given the problem we are discussing. Note additionally that this substance was not absorbed through the vaginal mucosa or through wounds [6, 7]. The medical product also contains another substance known in medicine - dexpanthenol. This compound is converted in tissues to pantothenic acid, which is part of coenzyme A and plays an important role in maintaining normal epithelial function, accelerating the regeneration of skin and mucous membranes. Dexpanthenol is absorbed fairly quickly when applied to human skin, and then immediately converted to pantothenic acid (in turn, is intensively distributed in human tissues in the form of vital coenzyme A). Pantothenic acid is excreted from the human body mainly unchanged in urine and feces [5, 8, 9].

It is important to note that octenidine dihydrochloride, depending on the form of release and method of application, is also included in various health care products, including drugs and disinfectants. Dexpanthenol is widely used in both the pharmaceutical and cosmetic industries due to its positive effect on the regeneration of the skin and mucous membranes. Thus, the medical device Prodexin, vaginal suppositories, contains the antiseptic substance octenidine dihydrochloride, which, according to the literature, has no systemic effects on the human body. Medico-biological effect of the substance on the body is associated with inhibition of the development of foreign microorganisms in the vagina, prevention of sexually transmitted diseases. The previously mentioned

substance dexpanthenol performs an auxiliary function, aimed at preventing the development of potential side effects due to the irritating effect of octenidine dihydrochloride. Therefore, the effect of the medical device Prodexin, vaginal suppositories, on the human body cannot be defined as pharmacological or immunological, as well as one that alters metabolism [5]. Therefore, this product can be considered a medical device in the sense of [2].

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