used on demand for the treatment of intermittent and acute episodes of asthma. The duration of action of these drugs is 4 hours. In case of insufficient efficacy of short-acting β2-agonists in exacerbation of asthma, they are combined with a cholinolytic - ipratropium bromide.

Medicines used for the treatment of asthma must comply with the provisions of the unified clinical protocol, which is developed in accordance with the Methodology for development and implementation of medical standards (unified clinical protocols) of evidence-based care, approved by the order of the Ministry of Health of Ukraine dated September 28, 2012 № 751 introduction of medical and technological documents on standardization of medical care in the system of the Ministry of Health of Ukraine "and on the basis of an adapted clinical guideline based on evidence" Bronchial asthma ", which provides best practice in providing medical care to patients with bronchial asthma. Most of these drugs are used in the form of inhalation forms using special devices - inhalers. This is primarily due to the fact that inhalation therapy is the optimal way to deliver the necessary drugs directly to the respiratory tract, as well as the presence of many advantages of this dosage form compared to others.

As a result of the analysis, it was found that the pharmaceutical market among the drugs for the treatment of asthma is dominated by imported drugs 67.60 % (48 drugs), and domestic drugs account for 32.40 % (23 drugs ¬ drugs). In turn, it was found that among imported drugs for the treatment of bronchial asthma, the leading position is occupied by the United Kingdom (19 %), second by India (13 %), third by Finland (11 %), a slightly smaller share by Lithuania (9 %). Germany and Poland occupy 8 % each, Israel, the USA and Sweden 6 % each, Slovenia and Switzerland 4 % each, and Turkey, Jordan, and Hungary 2 % each.

Conclusions. According to the recommendations of GINA experts (2017), the tactics and types of treatment for bronchial asthma are divided into steps, each of which corresponds to the severity of the disease and how asthma symptoms respond to therapy.

ANALYSIS OF REQUIREMENTS FOR THE PROCEDURE OF ASSESSMENT OF CONFORMITY OF MEDICAL DEVICES IN COMPLIANCE WITH EU REGULATIONS MDR 2017/745 AND IVDR 2017/746

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Introduction. In contrast to the market for medicines, the legislative development of the medical devices (MD) sector within the EU common market has taken place relatively recently. Compliance with European Union rules on product safety and the ability to trace non-compliant medical devices has been met in compliance with safety commitments, as well as greater integration, cooperation and assistance between public authorities. The main goal is that products placed on the EU market must be safe for the end user during use. In 2012, the Commission proposed two provisions on medical devices and in vitro diagnostic medical devices. On 5 April 2017, the European Parliament and the Council of Europe adopted and published on 5 May 2017 the EU MDR Regulation 2017/745, replacing the Medical Devices Directive № 93/42/EC and the Implantable Medical Devices Directive № 90/385/EC, and Regulation on Medical Devices EU IVDR 2017/746, which replaces Directive № 98/79/EC on medical devices for in vitro diagnostic use. From 26 May 2021, EU MDR Regulations 2017/745 and EU IVDR 2017/746 will enter into full force at the end of the transition period.

Aim. The purpose of the work is to analyze the classification and requirements for the procedure for conformity assessment of medical devices in accordance with EU Regulations MDR 2017/745 and EU IVDR 2017/746.

Materials and methods. In the process of performing the work, the methods were used theoretical generalization and retrospective analysis.

Results and discussion. Determining the risk class of a medical device is essential to determine the actions for MD marking (Article 51), especially when choosing a conformity assessment procedure and clinical requirements. The MDR sets out 22 rules for determining the risk class (Annex VIII), as opposed to the 18 rules set out in the Directive (see Annex A). Particular attention is paid to the rules on: invasive products, surgically invasive products, MD, which are implanted (Section 5: Rules 5-8); AMV (Section 6: Rules 9-13, for example, software now falls under Rule 11); articles that use tissues and cells (Rule 18); articles incorporating nanomaterials (Rule 19); and articles consisting of substances (Rule 21).

The IVDR classification differs significantly from the directive. In vitro diagnostic medical devices are divided into four classes: A, B, C and D according to their purpose and risk class (see Annex B). Conformity assessment of MD varies depending on the risk class and characteristics of certain products (Article 52). The involvement of a notified body is necessary for all high-risk products. In some cases, manufacturers have a choice of conformity assessment path. For some Class III and AMV products that are implanted, Class IIb has a new clinical evaluation procedure defined by independent experts on the basis of a clinical evaluation report by a notified body (Article 54).

The quality management system (paragraph 9 of Article 10) now includes clinical evaluation and post-marketing surveillance. Notified bodies must report to the competent authorities the certificates they have issued for Class IIb, III (57) and Class D (58) CFs. The report should include instructions for use, summary reports on safety and clinical trials, the NGO's report on conformity assessment, laboratory tests and the scientific report of the EU Reference Laboratory (Article 48 of the IVDR), as well as expert opinions (Article 106 of the MDR).

In order to present products on the European market, MD manufacturers must meet the requirements of the new technical regulation. The main difficulties that MDR and IVDR cause in manufacturers and ways to solve them are given below. The first problem for manufacturers is the reclassification of MD. The manufacturer must pay attention to the MDR and IVDR classification rules (the new classification rules are given in Annex A for MDR and Annex B for IVDR) to determine whether the MD class has changed and whether the new conformity assessment requirements apply to its product range. In the event of changes (MD has a different risk class for MDR or IVDR, or changes in the conformity assessment procedure), the manufacturer must contact the Notified Body (MDR and IVDR accredited by the European body) to specify the time required to perform all the necessary requirements of the technical regulations. The new regulations set requirements for clinical assessment, especially high-risk MD (class IIb and III). Clinical data should be proportionate to the risk associated with the use of this device. Unlike Medical Device Directive 93/42/EC , according to which the manufacturer had the right to use the results of clinical evaluation of equivalent products to register their MD, the requirements of MDR and IVDR limited this right, especially for high-risk products (class IIb, III, lists C, D). Conducting a clinical evaluation and reporting on clinical trials (and later supplementing them) is a necessity for all CFs, including those who have never been involved in incidents. Clinical evaluation can be performed by analyzing documentation and literature sources for low-risk MD (and only if the market already has an equivalent MD in all parameters, ie, intended use, settings and diagnostic capabilities.), however, if the manufacturer is unable to conduct the study in this way, he will need to conduct the study himself. The changes will require more financial and time effort.

Conclusions. This analysis is necessary for the development of proposals for improving the technical regulation of medical devices in Ukraine.

DEVELOPMENT OF MEASURES TO REDUCE THE RISK OF INFECTION WITH COVID-19.

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Introduction. In the new millennium, humanity has faced infectious diseases that no one knew about. Plague and typhus were replaced by dangerous viruses. In December 2019, a series of unexplained cases of pneumonia was registered in China. Subsequent studies have identified a new strain of coronavirus - SARS-CoV-2, which is the causative agent of acute infectious disease COVID-19. In a short period of time, the epidemic of a new coronavirus infection has grown into a pandemic that has spread to more than 200 countries. At the beginning of 2021, more than 2 million people died from this disease in the world. This is 2.2% of those who fell ill (96 million). Anti-infective systems help prevent disease and save lives. Coronavirus infection is an acute viral disease with a predominant lesion of the upper respiratory tract. Etiology: RNA virus of the genus Betacoronavirus of the family Coronaviridae. Natural reservoir: unknown. probably wild animals (bats, snakes, etc.). Source of infection: animals or sick people. Ways of transmission: airborne (virus secretion when coughing, sneezing, talking), airborne, contact. Transmission factors: air, food, household items. Incubation period: From 2 to 14 days, more often 2-7 days. According to the latest data, the disease becomes contagious 2-3 days before the onset of symptoms. Treatment: pathogenetic, symptomatic. The main reasons for the risk of Covid-19 infection among health care workers: lack of experience in working with respiratory pathogens; insufficiently strict disinfection measures; shortcomings of personal protective equipment; long working time (contact).

Aim. The aim of the work is to develop measures to organize the activities of some institutions and reduce the risk of infection with Covid-19.

Materials and methods. Mortality from Covid-19 varies from 0.1 to 17%. The dead included more elderly people over the age of 60 and people with chronic diseases. The WHO recommendations for the population in connection with the spread of the new coronavirus are considered. In the course of the study, we analyzed the current state of the SARS-CoV-II pandemic and the activities of international and regional authorities to reduce the risk of SARS-CoV-II infection. Possible risks and inconsistencies that lead to the spread of coronavirus have been identified and analyzed. A new practice of brainstorming in quarantine, or physical distance of participants, through online conferencing was applied. A brainstorming session was conducted to improve methods for preventing SARS CoV-II infection. A causal diagram was used for a detailed analysis of the results of the brainstorming.

Results and discussion. Recommendations for reducing the risk of coronavirus infection: Use personal protective masks or respirators, especially in crowded places and change them every 2-3 hours. Wash your hands thoroughly with soap and treat your hands regularly with an alcohol-based product after visiting public places and before each meal. Follow the rules of respiratory hygiene: when coughing and sneezing, cover your mouth and nose with a napkin or elbow bend; immediately throw the napkin in the trash can with a lid and treat your hands with an alcohol-based antiseptic or wash them with soap and water. Keep your distance in public places. Keep people at