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ISO CERTIFICATIONS FOR PHARMACEUTICAL BIOTECHNOLOGY PRODUCTION

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Introduction. In London in 1946, delegates from 25 countries met to discuss the future of international standardization. Officially, the International Organization for Standardization (ISO) was founded in 1947, with 67 technical committees. ISO's headquarters is located in Geneva, Switzerland. The first standard was published in 1951.

By the end of 2024, the organization unites national standardization bodies from 172 countries. It operates 841 technical committees and has developed 25,647 international standards covering virtually all aspects of technology and production. The motto of the International Organization for Standardization is: "Great things happen when the world agrees."

Results and discussion. ISO certification ensures pharmaceutical products comply with international standards, which is essential for export and collaboration. It confirms quality, boosts customer and partner trust, and strengthens a company's market position. ISO standards also help optimize processes, reduce costs, and improve resource management efficiency.

ISO does not certify companies directly. Instead, it develops standards, while certification is carried out by accredited independent organizations. The certification process involves an audit to verify that a company or product complies with the requirements of a specific standard.

For companies, ISO certification enhances efficiency, reputation, and competitiveness. For consumers, it ensures quality, safety, and compliance with international norms. For society, it promotes environmental protection, safe technologies, and improved quality of life. ISO is one of the most vital tools for fostering global harmonization, innovation, and sustainable development.

To ensure product quality, process safety, and compliance with regulatory requirements, pharmaceutical biotechnology production must adhere to specific international standards.

ISO 9001: Quality Management System – ensures efficient organization, documentation, and management of production processes to guarantee quality. ISO 45001: Occupational Health and Safety Management System – ensures worker safety during production processes. ISO 14001: Environmental Management System – regulates the environmental impact of production, minimizing harm. ISO 13485: Quality Management System for Medical Devices – required for companies producing medical devices or biotechnological products. ISO 17025: General Requirements for Laboratory Competence – ensures the competence of laboratories controlling the quality of pharmaceutical and biotechnological products. ISO 14644: Cleanrooms and Controlled Environments – establishes requirements for the design and control of cleanrooms used in production.

ISO 14971: Risk Management for Medical Devices – defines procedures for risk assessment and management in the use of medical and pharmaceutical devices. ISO 50001: Energy Management System – promotes energy consumption reduction and environmental sustainability. ISO 22301: Business Continuity Management – prepares organizations for crisis situations or disruptions. ISO 31000: Risk Management – focuses on managing risks in biotechnological production.

In addition to ISO, compliance with GMP (Good Manufacturing Practice) standards is mandatory in pharmaceutical biotechnology. These standards are the primary regulatory requirements in this field and are overseen by authorities such as the FDA (USA), EMA (EU), or the Ministry of Health (Ukraine).

Conclusion. ISO certification enhances competitiveness and efficiency. The selection of specific certifications depends on the type of product, target markets, and the specifics of production in the pharmaceutical industry.

PHARMACOECONOMIC ANALYSIS OF SELECTIVE IMMUNOSUPPRESSANTS FOR THE TREATMENT OF RELAPSING AND PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS

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Introduction. The problem of therapy for multiple sclerosis is extremely urgent in Ukraine, as this pathology ranks second in terms of disability among diseases of the nervous system. Timely diagnosis of MS in the initial stages and early appointment of adequate treatment can prevent the occurrence of exacerbations, slow down the progression of the disease and disability of patients. A key role in achieving maximum effectiveness of multiple sclerosis therapy is the patient's compliance with the prescribed indications for taking medications and the dosage regimen. Often, in the second and third years of therapy, patient compliance decreases to 75–80%, which can lead to a deterioration in the patient's condition and an exacerbation of the disease. A way out of this situation may be therapy with drugs with an innovative dosage regimen, which allows for annual short courses of therapy for 2 years and at the same time achieve long-term stable remission. Current treatments for relapsing-remitting multiple sclerosis include alemtuzumab, beta interferons, cladribine, dimethyl fumarate, fingolimod, glatiramer acetate, natalizumab, and teriflunomide.

The aim of the study is conducting pharmacoeconomic analysis of some selective immunosuppressants for the treatment of relapsing and primary progressive multiple sclerosis.

Materials and methods of research: systematic approach, structural-comparative and content analysis, cost-effectiveness analysis.

Results and discussions. The drug Ocrevus® (ocrelizumab) has demonstrated efficacy in treating relapsing-remitting multiple sclerosis (RRMS), supported by findings from numerous randomized controlled trials (RCTs). Results from these studies, conducted from the drug's introduction until November 2018, are available in databases such as PubMed, Embase, Web of Science, Cochrane, and ClinicalTrials.gov. Ocrevus® showed superior effectiveness, evidenced by a statistically significant reduction in relapse rates compared to other treatments, including interferon beta-1b, interferon beta-1α, peginterferon beta-1α, glatiramer acetate, and teriflunomide.

A pooled analysis of two trials showed that the proportion of patients with disability progression confirmed at 12 weeks was significantly lower with ocrelizumab compared to interferon beta-1α (9.1% vs 13.6%; hazard ratio: 0.60; confidence interval 95% CI: 0.45-0,81; P<0,001). Similarly, at 24 weeks, the percentage of patients with confirmed disability was also lower with ocrelizumab (6.9% vs 10.5%; risk ratio: 0.60; confidence interval 95% CI: 0.43–0.84; P=0.003). Additionally, ocrelizumab significantly reduced the mean number of gadolinium-enhancing lesions on MRI: 0.02 lesions compared to 0.29 with interferon beta-1α in ClR I (94% reduction, P < 0.001) and 0.02 versus 0.42 in ClR II (95% reduction, P < 0.001).

In Ukraine, a cost-effectiveness analysis model was adapted using the MS Excel-based “Cost-effectiveness/cost-utility model of ocrelizumab compared to alternative regimens in relapsing-remitting multiple sclerosis” derived from OPERA I and II clinical trial data. This adaptation involved identifying data on direct medical costs specific to Ukraine and incorporating these cost parameters