346. EVOLUTION OF ORGANOTHERAPY MEDICINES IN CURRENT PRACTICE

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Introduction: Worldwide, over 350 million patients have benefited from approved medicines manufactured through biotechnology. Currently, over 650 new biological medicines and vaccines are be developed to treat more than 100 diseases. Biologics are not new, development of human growth hormone, insulin, and red-blood cell stimulating agents occurred decades ago, but the targets have increased exponentially with new genetic information and new understanding of subcellular cascades and disease processes. Scientific fields used in developing biologics include genomics and proteomics, as well as microarray, cell culture, and monoclonal antibody technologies. The aim of the study is analysing of biological medicines technology process from organotherapy to new current practice of biotherapeutic products. Materials and methods: Has been conducted a descriptive cross-sectional study of different technological manufacturing methods during time of some biological medicines. Discussion results: Biotherapeutics, turned over, human conception about medicine possibilities since they opened new ways of diseases treatment, that recently have considered to be completely incurable. Patients with such terrible diagnosis like cancer, diabetes, multiple sclerosis, chronic kidney disease stage renal failure and others were able to fully recover or significantly improve the quality of life and increase its duration. First generation of biotherapeutics, were products of animals or vegetable origin, for example, bovine insulin, streptokinase, and others. Medicines, such insulin, thyroid hormone, testosterone, estrogen, pancreatin, heparin, have been originally obtained by extraction of animal organs. Since 1922, it has made considerable progress due to the discovery of new hormones produced in pure phase. Then came the products of human origin - growth hormone, antihemophilic factor VIII. The first biotech drug became recombinant human insulin, released on the pharmaceutical market in 1982. Scientific fields used in developing biologics include genomics and proteomics, as well as microarray, cell culture, and monoclonal antibody technologies. Increasing knowledge of genetics and cell processes leads to potential new biologic (and drug) targets at each step in the protein-production process. Today, under the biotherapeutic medicines, in international practice (for example, according to European Medicines Agency,) refers to immunobiological drugs produced by genetic engineering. In particular, for their production is used DNA recombinant technology, the method of controlled expression of other genes. Today there are more than 200 biotech drugs, thousands of new drugs are being studied in clinical trials and about 300 of them are in the final stages of research. About half of all medications developed in the world - biotech drugs. As the exclusive rights for these biological medicines (biotherpaeutics) expire, similar biological medicines, or “biosimilars”, are being developed, with some already available on European markets. The manufacturing process of biotech drugs, is very complex. To create a protein that will be used as an active ingredient in the biotechnological preparation is uses a unique line of living cells. The production process involves more than 5,000 critical stages, and for the preparation of quality control is used more than 2000 tests. In the production of biosimilar, practically is impossible to reproduce all the complex technology of production of the active substance, that is why it is necessary to conduct integrated quality control process. Conclusion: Biotechnological drugs - it's unique products, which significantly expanded the possibilities of modern medicine. Today, when the expire a number of

patents of original biotech drugs will appear inevitably biosimilar, what will increase the availability of biotech drugs to the population.

Key Words: medicines, biotherapeutics, organotherapies, biosimilar.

347. THE IMPACT OF HEALTH TECHNOLOGY ASSESSMENT ON THE AVAILABILITY OF EXPENSIVE DRUGS

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Introduction: Inefficient pharmaceutical policies and use of medicines is one of the top sources of ineffectiveness in health systems. Spending on health cannot increase infinitely, there are always various constraints on the supply of health services. When resources are scarce relative to needs because of a limited budget, the use of resources in one way prevents their use in other ways. Health Technology Assessment (HTA) attempts to give decision-makers some notion of the value of investment decisions in healthcare. The aim of this study is to evaluate the role of HTA on the introduction of high cost medicines trough universal health coverage.

Materials and methods: It was conducted a cross-sectional descriptive study with the evaluation of procedures, equipment, medications and an interdisciplinary approach that includes analysis of safety, costs, and efficiency. Sources: government organizations data, human and organizational resources, technologies providers, biomedical database, centre's practicing evidence-based medicine, etc. Discussion results: As the medicines are the main drivers to out-of-pocket health payments, and consequently, to catastrophic and impoverishing medical expenditures, the main goal of HTA strategies is to improve the access to essential, quality health technologies including medicines and medical devices – that are fundamental part of every person's right to health. As a starting point, most HTA processes consider the additional health benefits as a way of understanding the value of the recommendations they need to make. HTA processes, those considering coverage for new medicines, examine the economic impact (costs) of decisions to pay for new medicines. Many health systems have been developed guidance for economic evaluation, to ensure estimates of costs and effects of paying for new medicines are derived in a clear and consistent manner. This avoids a situation where an evaluation of one medicine looks more attractive than another, simply because the researcher used different underlying assumptions and approaches. There are 125 focal points of HTA around the world, from which 53 are located in European region. The mains purpose of HTA undertaking is planning and budgeting, reimbursement/package of benefits and clinical practice guidelines and protocols. Around 95% of countries use HTA for medicines evaluation, most frequently is used in high income countries (89%) but in low income countries the tendency is significantly lower (62%). Safety (53%-92%), clinical effectiveness (65%-85%), and economic and budgetary impact (45%) are the main components evaluated with HTA. Practically in all countries, for new/original/innovator/without comparator medicines are used as HTA instrument: budget impact analyses, cost-effectiveness analysis and cost-utility analysis (typical for UK). As different states have different ways of accepting evidence and interpreting it, variations exist in the application of HTA appraisals, and these can result in diverging coverage decisions for the same pharmaceutical across different state. There are some limitations on the