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

use of HTA for new/expensive medicines, it may be difficult to perform satisfactory HTA due to the limited amount of available evidence. The regulator can then decide not to reimburse this drug. However, this may prevent patients from accessing certain promising drugs. In this context "risk-sharing" or "performance-based" agreements are the mechanisms addressing this problem. These schemes intend to protect insurers, while enabling patients to have access to these innovative medicines under certain circumstances.

Conclusion: To increase access to new medicines, countries have to perform HTA in policy and decision-making, especially on how best to allocate limited funds to health interventions and technologies; including a new medicine into a reimbursement scheme, evaluation scheme, rolling-out public health programmes, priority setting in health care, setting medicine prices based on their cost–effectiveness, and formulating clinical guidelines. Key Words: Health technology assessment, new medicines, reimbursement.

348. MANAGEMENT OF BREAST CANCER SYSTEMIC THERAPY

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Introduction. According to the World Health Organization(WHO), breast cancer is the most common cancer in women worldwide, with an increased incidence especially in developing countries, where most cases are diagnosed at later stages with, nearly 1.7 million new cases diagnosed in 2012. It was estimated that worldwide more than 508,000 women died in 2011 from breast cancer. Breast cancer is the leading cause of cancer death among women in developing countries and the second leading cause of cancer death among women in developed countries.

The aim of the study is establishment of worldwide common practices of breast cancer systematic therapy. Materials and methods: The study presents a descriptive case study analysis, of available breast cancer therapy, especially in developing countries according with WHO List of Essential Medicines (LME) recommendation.

Discussion results: In 2015, 16 new medicines for treating cancers were added to the WHO model of LME, a strong challenge for governments to step up cancer care and guide national efforts to strengthen their health systems. Systemic therapy for breast cancer includes chemotherapy, hormone therapy, and targeted biological therapies. New cancer medicines included in LME was: imatinib (for chronic myelogenous leukemia), rituximab (for some types of non-Hodgkin's lymphoma) and trastuzumab (for a common subtype of breast cancer). For breast cancer systematic therapy, WHO recommend: cytotoxic and adjuvant preparations: Capecitabine, Carboplatin, Cyclophosphamide, Docetaxelum, Doxorubicinum, Fluorouracilum, Methotrexatum, Paclitaxelum, Trastuzumabum, Vinorelbinum; hormones and anti-hormones: Anastrozolum, Leuprorelinum, Tamoxifenum. Overall, 84 % and 74 % of developing countries had at least one chemotherapeutic and one hormonal agent for breast cancer. Slightly fewer than 10 % of the countries had a HER2-targeted therapy as essential medicine. Tamoxifen, anthracylines, cyclophosphamide, methotrexate and fluorouracil, doxorubicin