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

were well represented with inclusion in more than 70 % of the national EML as opposed to inclusion in below 30 % for all other main regimens. Taking into account tumor size, extent of spread, and patient preference, treatment usually involves breast-conserving surgery or mastectomy; in addition, radiation therapy, chemotherapy (before or after surgery); hormone therapy; and/or targeted biologic therapy may be used depending on the stage of the cancer, its biologic characteristics, and the type of surgery used. Effective breast cancer treatment is limited by small numbers of specialized medical personnel; insufficient modern equipment, and the high cost of cancer drugs. Chemotherapy is dependent on multiple factors, such as: size of the cancer, the number of lymph nodes involved, the presence of hormone receptors, and the amount of human epidermal growth receptor 2 (HER2) protein made by the cancer cells. Women with ER+ breast cancer have to administer hormone therapy such as tamoxifen or aromatase inhibitors. The use of the HER2-targeted monoclonal antibody-based treatment trastuzumab together with chemotherapy has been shown to be highly effective in treating HER2-positive cancer, but is cost-expensive in majority of countries. Despite substantial progress made in treatment possibilities, breast cancer survival is still poor in developing countries. This might be due to lack of access to different components of care including systemic therapy.

Conclusion: National cancer plans should define health care networks in which centers of excellence become connected through outreach to rural and surrounding areas for consultation and patient triage. Public awareness that breast cancer outcomes are improved through early detection should be promoted in conjunction with the development of resource-appropriate early detection programs. Diagnostic services, surgical treatment, radiotherapy, systemic therapy, and palliative care should become integrated within coordinated multidisciplinary environments.

Key words: breast cancer, essential medicines list, developing countries.

349. THE PHARMACEUTICAL INDUSTRY ROLE IN ENSURING ACCESS TO MEDICINES IN DIFFERENT COUNTRIES

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Introduction: Different aspects of medicines pricing regulation often represent an obstacle of the patient access to medicines, especially in the developing countries. The main objective of medicines price regulation is to cope with rising health expenditures. Thereby, drug manufacturers, refusing to be present in these markets restraint and preventing access to vital medications and essential medicines. The purpose of the study is evaluation of international medicines pricing regulation carried out between health systems and the pharmaceutical industry.

Materials and methods: Has been carried out a descriptive analysis on medicines pricing regulation in different countries in order to determine potential methods of collaboration between pharmaceutical industries and local decision makers. Discussion results: Access to medicine depends on each country's unique capabilities, including the government policies and various factors: availability, affordability, accessibility and quality/acceptability. Most European countries employ a huge variety of regulation measures at the same time both on the demand and on the supply side: supply side regulation: