aspect of the pharmaceutical industry. After the reform policy in 1978, both the governmental regulators and the regulated pharmaceutical industry became development-oriented. The effective control of the quality and safety of pharmaceutical products became a serious problem. In order to reverse the situation China tried to establish an independent drug regulatory system. **CONCLUSIONS:** Because of path dependence it is very difficult to turn the drug regulatory system from the system of unification of the regulators and the regulated into an independent system. The introduction of a formally independent regulatory system has improved the regulator's motive to supervise the quality and safety of drugs to some extent. But many impediment factors still exist both inside and outside China's drug regulatory system. The great difficulties to establish an effective drug regulatory system China experienced during the past 10 years proved that the old way in which the government regulatory agencies operate is very difficult to shake. The policy maker should fully understand the impact of the previous system and make a long and Coordinative effort. The best way to establish a good independent drug regulatory system has to be a gradual rather than a radical reform.

PHP123

PERSPECTIVE OF SOCIAL PARTICIPATION IN THE EVALUATION PROCESS OF INCORPORATING TECHNOLOGY IN HEALTH CARE

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OBJECTIVES: The Brazilian Public Health System (SUS) was established in 1988, thereby ensuring that the citizen universal right to health, having as one of its principles to the participation or social control. The performance of the SUS in the field of evaluation and incorporation of new technologies represents the public interest as defined by universal policies are committed to the equity and based on scientific knowledge consistent. The year of 2011 represented a breakthrough in transparency and social participation in the process of incorporating technology with the publication of Law no. 12,401, of 28/04/2011, which has set up a National Commission for the Incorporation of Technology in the SUS/CONITEC. The aim of this study was to identify in the participation of public consultations of CONITEC, the civil society participation, public and private institutions. **METHODS:** This is a descriptive, cross-sectional study, which was developed from the analysis of technical reports of Conitec which related to public consultation by the committee were extracted data to support decision-making on technology incorporation in SUS. **RESULTS:** In the years 2012 and 2013, 78 public consultations and more than 4,182 contributions were examined by CONITEC published arising from health care institutions, patient association, educational institutions, medical societies, etc, that recommended to incorporate 64 new technologies in the SUS. **CONCLUSIONS:** The Ministry of Health, responsible for enforcement of the law n. 12.401, use systematically the public consultations as the instrument to gather contributions from segments of society in their process work. To the extent that such participation is intended to subsidize the decision about incorporating technology in the SUS, there are significant gains in building the public policy agenda, adding legitimacy and transparency in government decision-making.

PHP125

HIGH-COST MEDICINES IN BRAZIL: CENTRALIZED PURCHASE FOR OPTIMIZATION OF BUDGETARY RESOURCES AND INCREASING ACCESS IN THE PUBLIC HEALTH SYSTEM

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OBJECTIVES: The Brazilian public health system ensures universal, equitable and comprehensive access to health technologies, including medicines. The high-cost medicines are offered through Specialized Pharmaceutical Services Component (SPSC). The clinical conditions treated in the SPSC are defined in the Guidelines in the form of lines of care. To describe the experience and results of the SPSC with its particular strategies in the quest for the comprehensive health care. **METHODS:** Focused on the SPSC's issues, we did a retrospective data analysis related to its management strategies for the pharmaceutical services in the public health system in the period 2010 to 2013. Data were obtained from documents of the Ministry of Health in 2013 (current values; exchange rate: US$ 1 = R$ 2.30). **RESULTS:** As a strategy to increase medicines access and optimization of resource allocation, the MoH expanded the amount of centralized procurement medicines, from 13 to 51 products. This deed was focused on those medicines with a concentrated market. As a consequence, this action allowed a saving of U$ 403.8 million in four years, compared to the price in 2010. The medicines that most contributed to the economy were adalimumabe (U$120 million), etanercepte (U$100 million) and infliximab (U$44 million). Betainterferona (52%), etanercepte (48%), imiglucerase (48%), adalimumabe (37%) e Alfapeginterferona (37%) were the products with a greater reduction in the unit price, considering the accumulated value at period. The increase in the number of units distributed was 263%. **CONCLUSIONS:** The SPSC was designed in 2010 for the budgetary resources optimization and to expand access to medicines for diseases that require complex health services or high-cost medicines. The purchasing power of the MoH is a strategy that allowed expansion of access to medicines, with optimization of budgetary resources in the Brazilian public health system.

HEALTH CARE USE & POLICY STUDIES – Conceptual Papers

PHP127

PRAGMATIC MCDA COMBINED WITH ADVANCED PHARMACOEPIDEMIOLOGY FOR QUANTITATIVE BENEFIT/RISK ASSESSMENTS OF MEDICINES

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OBJECTIVES: Many initiatives (e.g., PROTECT, EFSPI) are exploring quantitative methodologies to conduct benefit/risk assessments of medicines. Objectives of this study were to combine quantitative methodologies that can capture expert knowledge and decisionmakers insights to genuinely support real-world decisions. **METHODS:** Using the case study of efalizumab, approved by the EMA in 2004 for the treatment of plaque psoriasis and withdrawn in 2009, a pragmatic methodology was developed that combines advanced pharmacoepidemiology and MCDA for quantitative benefit/risk assessment. Development involved application of: MCDA principles to ensure applicability to any therapeutic area, comparability across medicines, and portability over product cycle (re-evaluation); and advanced pharmacoepidemiology and Bayesian modeling to identify/generate most useful data. Overarching design was guided by ethical implications of criteria and data selection as well as applicability in real life settings including face validity, time constraints, complexity and transparency. **RESULTS:** The hierarchical multicriteria model consists of two major domains: Benefits (favourable effects, covering the criteria Clinical efficacy/effectiveness and Patient Reported outcomes); and Risks (unfavourable effects – criterion Safety). The safety criterion is subdivided into three generic subcriteria (Adverse events, Serious AEs and Fatal AEs). The benefit criteria are subdivided into specific subcriteria that correspond to the most relevant outcomes for a treatment for plaque psoriasis. All performance are assigned relative to existing alternatives or placebo. Each subcriterion contributes to the output of the model, the Benefit/Risk Estimate, which is the sum of normalized weights for each subcriterion multiplied by the respective performance score. Pharmacoepidemiology data is provided in a standardized format for each subcriterion and includes meta-analytic comparative statistics based on clinical trials, observational data and Bayesian models. Uncertainty is explored in sensitivity analyses. **CONCLUSIONS:** Integration of pragmatic MCDA modeling with advanced pharmacoepidemiology allows quantitative benefit/risk assessment that can be applicable and meaningful in real life regulatory settings.

PHP128

ASSESSING THE IMPACT OF A MULTI-MILLION PUBLIC-PRIVATE PARTNERSHIP FOR TRANSLATIONAL RESEARCH: THE CENTRE FOR TRANSLATIONAL MOLECULAR MEDICINE (CTMM)

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OBJECTIVES: The Center for Translational Molecular Medicine (CTMM) is a multi-million public-private partnership, including universities, academic hospitals, pharmaceutical and medical technology companies. CTMM aims to accelerate molecular diagnostics and imaging technologies to enable determination of predisposition, early diagnosis, and personalized treatment of patients. It is unique in that it mandates early Health Technology Assessment (HTA) in each of its 21 projects. This study assessed the impact of CTMM on scientific, translational, clinical and economic aspects. **METHODS:** The impact assessment was guided by the "Research Impact Framework" (Kuruvilla 2006) Objective data were gathered from extensive CTMM administrations, including publications, patents, project proceedings, early HTA results, etc. Perceived impact was investigated using a CTMM-wide survey (n=167) and two focus groups. **RESULTS:** CTMM focuses its impact on disease areas with high Disability Adjusted Life Years and high societal costs, i.e. oncology, cardiovascular, neurologic, infection and immunity diseases. Its scientific impact is as high as the overall impact of Dutch biomedical research, i.e. 15%-80% above international volume and journal impact standards. CTMM is perceived to stimulate and accelerate translation of technology to the clinic, with a median score of 4 out of 5 (IQR 3-5). Its main strength lies in pre-clinical and phase 1 development (median score 4 of 5; IQR 4-5). CTMM has generated nearly 1900 FTE of translational R&D capacity between 2008-15. Experience with and impact of early HTA varies widely between projects (median score 3 of 5; IQR: 2-4). CONCLUSION: By facilitating and managing effective and safe public-private collaboration, CTMM has demonstrated a solid scientific impact. Its impact on translational, (future) clinical and economic aspects is generally perceived as large. Metrics to objectively measure this need improvement as well as longer follow-up. The early HTA analyses have provided critical insights and exemplar approaches for future early HTA work in public-private partnerships.

PHP129

HOW TO CONSIDER EQUITY IN DECISIONS TO INCORPORATE NEW TECHNOLOGIES IN BRAZILIAN UNIFIED HEALTH SYSTEM (SUS)?

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OBJECTIVES: In 2011 was published 12.401 Law establishing the National Committee for Technologies Incorporation in SUS (CONITEC) and defining the criteria and deadlines for the analysis and adoption of technologies. According to the law, CONITEC's assessment must considers necessarily scientific evidences about efficacy, accuracy, effectiveness and safety of technologies and economic evaluation studies of benefits and costs in relation to the technologies already incorporated in SUS. Studies of economic evaluation traditionally ignore equity in health, and because this gap, researches have been undertaken to develop methods to incorporate equity into economic evaluation in health. Thus, this paper aims to analyze the viability of using an economic evaluation framework in the decision making process about incorporating technologies so that the equity is maximized within the Brazilian Unified Health System. **METHODS:** To fulfill this goal, review the scientific literature for methods to incorporate equity into cost-effectiveness was conducted with subsequent discussion how the methods found can be applied in the context of SUS, a system that offers universal coverage to approximately 201 million citizens. **RESULTS:** Until end of 2013, CONITEC recommended the incorporation of 64 technologies for diagnosis, prevention and treatment of various diseases, and no study of economic evaluation submitted addressed the issue of equity. By the research found a systematic review conducted by Johri & Norheim (2012) having found three distinct approaches: integration of distributional concerns through equity weights and social welfare functions, exploration of the opportunity costs of alternative policy options, through mathematical programming and multi-cri-