

## RESEARCH CONFERENCES

ESF-IfW Conference on the Global Health  
Economy

# The International Regulation of New Medical Technology: Health Technology Adoption in the European Union, North America, East Asia, and in the Developing World

Salzau Castle, Salzau (near Kiel) • Germany  
7-10 May 2007

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## Welcome Address

by Dr. Gitta Trauernicht



Dear Ladies and Gentlemen,

I am very pleased to be able to welcome high-caliber researchers from all over the world to Schleswig-Holstein for the second time. You obviously enjoyed your last conference here, and the conference organizers have once again chosen to hold your conference, this year on the International Regulation of New Medical Technology, at the Salzau Castle.

This must have something to do with the fact that Schleswig-Holstein is such a good place to be. Not only is it a wonderful place to spend a vacation or engage in some healthy recreation, it is a great place to pursue new developments, innovations, and projects. Everyone involved in health care here, be it in health care provision, health care service management, or in health research, works hand in hand with each other, for the good of people in Schleswig-Holstein and elsewhere. Schleswig-Holstein has successfully positioned itself as a national and international center of excellence in health care and a variety of health-related industries. With innovative products and practically oriented research, Schleswig-Holstein is leading in many areas of the life sciences.

Internationally renowned companies in medical technology with special strengths in precision surgery, implantology, and anesthesiology are at the heart of Schleswig-Holstein's achievement. The biotechnology industry has also taken root with considerable success here in the north. Universities and industry are working hand in hand in search of new chemical substances for the pharmaceutical industry, improved diagnostic devices, and promising new therapies for life-threatening diseases.

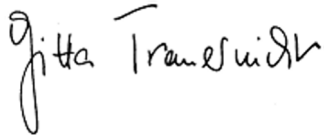
In Schleswig-Holstein, numerous private companies, university-based researchers, and hospital clinicians are working together closely on new medical products and methods for the welfare of patients. New standards in research and science are being set by the FUSION project at the Lübeck campus of Schleswig-Holstein's University Hospital, where new procedures for gentle liver surgery are being tested, and by the Inflammation at Interfaces Cluster of Excellence at the University of Kiel, which investigates the role of inflammatory processes and diseases in the human body. Another example of excellence is provided by the Fraunhofer Task Group on Cellular Differentiation and Cellular Technology at the University of Lübeck, which is concerned with the isolation and characterization of adult stem cells.

Schleswig-Holstein's University Hospital is the second biggest university hospital in Germany. A variety of internationally renowned science and research facilities, such as the Leibniz Research Center for Biomedicine at Borstel and specialized hospitals all over Schleswig-Holstein, are helping to push the frontier of medical knowledge.

Our state recognized long ago the enormous opportunities that the growing health care market of the future will provide. To capitalize on these opportunities, we have founded a strategic advisory council with members from industry, academia, and government. This council is the Gesundheitsinitiative Schleswig-Holstein. In a joint effort with delegates from physicians' associations, hospitals, health insurers, and other companies in the health care industry, as well as from research centers, chambers of industry, and professional associations, we aim to systematically expand Schleswig-Holstein's competences and to enhance the quality of health care in Schleswig-Holstein. Close cooperation between health care providers and health-related industries has long been a defining characteristic of health care in Schleswig-Holstein and continues to strengthen our profile as a health care state.

This conference, which has been organized by the Kiel Institute for the World Economy and the European Science Foundation, fits perfectly into the context of our state, and we are therefore happy to support it with financial resources from the Gesundheitsinitiative.

I wish you a successful conference.

A handwritten signature in black ink that reads "Gitta Trauernicht". The signature is written in a cursive style with a large initial 'G'.

Dr. Gitta Trauernicht

Minister for Social Welfare, Health, Family, Youth, and Seniors in the State of Schleswig-Holstein.

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**Introducing Immune Modulatory Interventions Including Vaccines and Vitamin A in High-Mortality Countries: Product Or Context?**

Peter Aaby and Christine Stabell Benn, Statens Serum Institut, Denmark; and Bandim Health Project, Guinea-Bissau

Based on nearly 30 years of epidemiological studies of health interventions in areas with high child mortality in West Africa, we will argue that too much emphasis is put on evaluations of the effectiveness of medical products in relation to the targeted problem and not enough emphasis on how health interventions might interact with other environmental conditions for the intervention.

Vaccines have only been evaluated in terms of their disease-specific preventive effects. However, vaccines have non-specific immunomodulatory effects. For example, measles vaccines have major beneficial effects on childhood survival in high-mortality areas which cannot be explained in terms of the prevention of measles infection. On the other hand, the high-titre measles vaccine (HT-MV) recommended by WHO in 1989 was associated with two-fold higher mortality in girls compared with standard measles vaccine (MV). It made no difference for boys. This was likewise a non-specific – but detrimental – effect since the new vaccine was fully protective against measles infection. When similar results were found in Guinea-Bissau, Senegal, Haiti and Sudan, WHO had to withdraw the HT-MV in 1992. Implementation of the HT-MV would probably have increased child mortality with at least ½ million additional deaths per year in Africa alone. Subsequent studies have found that most of the other routine vaccines including BCG, diphtheria-tetanus-pertussis (DTP), oral polio vaccine (OPV), hepatitis B vaccine (HBV), and inactivated polio vaccine (IPV) have non-specific effects as well. In general, live vaccines have beneficial non-specific effects whereas inactivated vaccines have no such effects. Furthermore, these effects are usually different for boys and girls as illustrated by the HT-MV story. Apparently vaccines not only induce specific immunity but also stimulate the general immune system and this effect is different for boys and girls.

Vaccines are routinely administered together. However, we have repeatedly found that effects might differ if a live and an inactivated vaccine are given together. For example, administering MV together with DTP is associated with 2-3 times higher mortality than receiving only MV. The sequence of vaccinations may also be important. The effect of vaccines may also depend on interaction with other immune stimulatory environmental conditions, for example effects are likely to differ by season. Furthermore, administering vaccines together with vitamin A as is currently recommended by WHO have major non-specific effects as indicated by several recent studies from West Africa.

Taking the non-specific effects into consideration might have major implications for current vaccination programmes and child mortality in low-income countries. Ideally the introduction of new medical technology with immunomodulatory implications should assess the effect on the immune system and on overall child mortality. Furthermore, it should be examined whether effects differ for boys and girls and whether the product interacts with common interventions in the relevant age group. Not taking these things into consideration could lead to the introduction of effective specific interventions which yet increases overall child mortality. It could also lead to the rejection of interventions which might be highly effective for one subgroup, say boys, but had the opposite effect for girls and therefore had no overall effect.

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**Social and Ethnic Differences in Attitudes to Prenatal Testing and Termination of Pregnancy**

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**Background:** Advances in DNA technology mean that a wider range of prenatal tests will soon become available. Obtaining separate informed consent for each condition is likely to cause confusion and provoke considerable anxiety amongst parents. Therefore, we set out to devise a classification system that could be useful in obtaining generic consent for similar conditions. In order to devise such a classification system, we compared the attitudes of women from two different ethnic backgrounds to prenatal testing and termination of pregnancy for a range of conditions, to see if "clusters" of attitudes to different conditions could be identified, for which prenatal testing might be offered as a package. **Methods** Four hundred and twenty white and Pakistani women living in the UK, who had recently had a baby, were surveyed about their attitudes to prenatal testing and termination for 30 different fetal conditions. **Findings:** Quantitative results are presented comparing the attitudes of different social and ethnic groups towards prenatal testing and termination of pregnancy for the range of disorders. Pakistani women held more favourable attitudes to prenatal testing, but less favourable attitudes to termination than their white counterparts. Both groups were most in favour of termination for the same four conditions: anencephaly, trisomy 13 or 18, quadriplegia, Duchenne muscular dystrophy. Advanced statistical analyses were used to measure how closely associated the 30 conditions were in respondents' answers. **Conclusion:** Variations in women's attitudes show the difficulties in designing a classification system to obtain generic consent. Variations in women's experiences, values and opinion for the different conditions has implications for obtaining informed consent. **Research in developing countries:** Developing countries are beginning to think more and more about the implementation of antenatal genetic screening, however, there is a paucity of research on the psychosocial impact of such health technology within these countries. We are currently involved in similar research to our UK study in Pakistan.

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**Research and Innovation Behaviour of German Medical Devices Industry – Empirical Analysis and Health Policy Assessment**

1. Rationale: Germany is a traditional location for medical devices enterprises. The medical devices industry is actually one of the most expanding sectors in the international health care market besides the pharmaceutical industry. Enterprises from Germany are more and more in strong competition with firms from USA, Japan and other EU-States.

2. Objectives: Health care markets are characterized by regulation, cost containment and budgeting. Considering this public policy I analyse the Research and Development (R&D) as well as the innovation behaviour of German medical devices enterprises empirically. My study has following question: Which economic factors determine operational R&D investments as well as the development of new medical devices ?

3. Methodology: My methodical approach is based on multivariate probit and tobit regressions. Dependent factors are R&D Participation, R&D Intensity as well as product and process innovations of medical devices firms. My empirical analysis uses a Panel-Dataset 2003 of the Centre for European Economic Research (ZEW Germany) with 2000 enterprises, which includes 200 medical devices firms. ZEW collects valide data in cooperation with OECD and EUROSTAT and they defines international comparable indicators for R&D activity and innovation activity. Independent Variables of my estimations are (1) firm size (2) product diversification (3) demand expectations (4) international demand (5) technological opportunities (6) own R&D absorptive capacities. Especially (5) technological oportunites are key factors for R&D based product innovations in the economic literature. Deep cooperations and high information flows between scientific institutions, competitors and customers seems to be extraordinary important for innovations activities of the medical device industry. A comparison of the German medical industry and the German manufacturing industry completes the empirical study and concludes all significant effects.

4. Results: (1) Firm Size is an important key factor for R&D and innovation activities of medical devices industry (2) The R&D and innovation activity especially depends on demand expectations of the firms (3) Cooperations strengthen the technological opportunities of the developing firms and increase the R&D and innovation activity.

5. Conclusions: The research and innovation behaviour of medical devices industry depends on several factors. Most of these factors are market based, whereas regulation like cost containment policies become more and more important. German firms innovate more if the demand expectations are high, the technological

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**Empowering High Risk Youth in Pakistan**

**Introduction:** As poverty continues to grip Pakistan, the number of urban street children grows and has now reached alarming proportions, demanding far greater action than presently offered. Urbanization, natural catastrophe, drought, disease, war and internal conflict, economic breakdown causing unemployment, and homelessness have forced families and children in search of a "better life," often putting children at risk of abuse and exploitation.

**Objectives:** To reduce drug use on the streets in particular injectable drug use and to prevent the transmission of STDs/HIV/AIDS among vulnerable youth.

**Methodology:** Baseline study and situation assessment of Health problems particularly HIV and STDs among street children of Quetta, Pakistan.

**Activities & Conclusion:** The program launched a peer education program, including: awareness of self and body protection focusing on child sexual abuse, STDs/HIV/AIDS, life skills, gender and sexual rights awareness, preventive health measures, and care at work.

Relationships among AIDS-related knowledge and beliefs and sexual behavior of young adults were determined. Reasons for unsafe sex included: misconception about disease etiology, conflicting cultural values, risk denial, partner pressures, trust and partner significance, accusation of promiscuity, lack of community endorsement of protective measures, and barriers to condom access. In addition, socio-economic pressure, physiological issues, poor community participation and attitudes, and low education level limited the effectiveness of existing AIDS prevention education.

**Recommendations:** It was found that working children are highly vulnerable to STDs/HIV/AIDS, as they lack protective measures in sexual abuse and are unaware of safe sexual practices. Training of adolescent as peer educators is recommended. Ours being an Islamic society, such information should be given to youth in a way that does not challenge local norms and values. Problem-based learning and participatory education for improving knowledge and condom use and community-based interventions should be considered for STDs/HIV/AIDS prevention.

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**The Introduction of New and Emerging Health Technologies in the Basque Country. A Three Sided Strategy.**

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The incorporation of new and emerging technologies in the Health Systems has been a matter of discussion in the last years. Many proposals have been considered such as: the application of legal regulations, the identification an early assessment of new technologies and the creation of monitoring systems that (taking into account the competences of funding organisms and health providers) guarantees the quality, safety, effectiveness and efficiency of health provision.

**Aim:** to design and analyse a strategy for the introduction of new and emerging technologies in the Basque Country.

**Methods:** we performed a systematic review and obtained information from different health systems. The main issues in this process were the benchmarking with other national and international organizations, the use of a multidisciplinary vision, the search for consensus between health planning and management sphere and, also between the clinical and policy level in our context. Then, we established the dimension of a local network for the identification of new and emerging technologies and made the recruitment of the volunteers.

**Results:** a three sided strategy has been designed which comprises early warning, regulation (regulatory law) and the creation of a monitoring system. The three phases are interconnected; the early warning system informs the decision of the advisory committee created through the regulatory law and just in case of uncertainties of effectiveness and standardization, the technologies are monitored. Four technologies have been considered by the regulatory commission and two of them have been finally monitored (verteporfin and apheresis for IBD). We have observed significant differences in the diffusion rates when compared with other health services nearby.

**Conclusions:** The introduction of new and emerging technologies in the health systems has to be considered in order to prevent incorrect diffusion of some technologies and unnecessary costs for the health systems. Our strategy is feasible and has obtained promising preliminary results.

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**Optimal Sequencing of Antiretroviral Treatment Under Uncertainty and Irreversibility**

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This paper develops an optimal sequencing rule for Antiretroviral Monotherapies by incorporating the possible development of resistant mutations, constituting irreversibility, and death of a patient, constituting uncertainty. The essence of the analysis is to assess the cost effectiveness of ART monotherapies recommended by the World Health Organization (WHO) vis-à-vis that of a proposed set of procedures that improves on the WHO recommendation by incorporating direct and indirect costs associated with a sequence of monotherapies. The analysis draws from a theory of investment under uncertainty and irreversibility that incorporates the costs of the development of resistant mutation and uncertainty with respect to the effectiveness of the treatment. The results show that incorporating such costs and uncertainty calls for earlier introduction of the first treatment, earlier withdrawal of any preceding treatment and replacement with succeeding treatment and sequencing of a more expensive treatment first.

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**The Impact of New Drug Launches on the Loss of Labor from Disease and Injury:  
Evidence from German Panel Data**

Van Bui and Michael Stolpe

This paper studies the evolution of early retirement due to disease and injury in the German labor force between 1988 and 2004. Using data from the German Federation of Public Pension Providers, the IMS Health Drug Launches database and the WHO Mortality Database, we show that new drug launches have substantially helped to reduce the loss of labor at the disease-level over time. We employ a variety of econometric methods to exploit the pseudo-panel structure of our dataset and find that in Western Germany alone each new chemical entity has on average saved around 200 working years in every year of the observation period. Controlling for individual determinants of health-related retirement, such as worker's age, sex and type of work, we also find evidence that the 2001 reform of pension laws has led to further reductions in the loss of labor from disease and injury.

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### **A Determination of Topics for Health Technology Assessment in Thailand: To Do What We Didn't Know And To Know What We Didn't Do**

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**Introduction:** Given resource constraint in health technology assessment (HTA), the procedure for the selection of HTA topics can be seen as a crucial part, because not only it is the first step of HTA per se, but also the topics for assessment themselves need to be policy relevant so that the assessment findings can properly assist decision makers in making policy decisions. This concern is increasingly recognised in Thailand where empirical evidences demonstrated a poor distribution of research resources to determine the cost-effective interventions for diminishing disease burden within the areas of major health problems. As a result, Health Intervention and Technology Assessment program (HITAP), which is a newly established HTA agency in Thailand, has tried to develop the mechanisms for HTA topic selection that is systematic, transparent and participatory.

**Objective:** An overall aim of this study was to describe quantitatively and qualitatively progression and findings from HTA topic selection process recently developed by HITAP.

**Methods:** The process involved potential users of HTA information namely (1) third party payers (public health insurers), (2) national health care program managers (Ministry of Public Health's Departments) and (3) HITAP funding organizations. In December 2006, these key players were invited to submit the topics needed to be assessed based on their considerations. The submitted topics were reviewed and prioritised by HITAP researchers in January 2007, using several preset criteria such as the potential policy implications of the assessment results, the magnitude of health and financial burdens, and the duplication of prior assessment. Furthermore, a consultation workshop was conducted on February 9<sup>th</sup>, 2007 that allowed the representatives from those organisations submitted the HTA topics to provide justifications and prioritize their own list of top ten HTA topics needed to be assessed in 2007. Results from each organisation were analysed and the final list made by workshop participants were compared with the list made by HITAP researchers.

**Results:** Fifty one topics were submitted from ten organisations. However, only 29 distinct HTA topics were met inclusion criteria and then included in the priority setting process. Most topics were pharmaceuticals (51%), medical procedures (24%), medical devices (15%) and health policy (10%). Although the potential financial burden generated by the health technology was a main concern from participants, several aspects such as socio-cultural implications, consumer rights, equity, ethics, as well as potential misuse and associated problems of drug resistance were relevant when priority setting of HTA topics was considered. At final, six out of ten topics selected by HITAP researchers were the same as those made by the representatives from public health authorities.

**Conclusion:** Findings from this study illustrated the possibility to make HTA topic selection process to be systematic, transparent and participatory, which would eventually increase the usefulness and credibility of HTA. In addition, it emphasized a notion that HTA should be seen as the co-responsibility between HTA researchers and users toward the appropriate use of health technology.

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## **How Do Economic Incentives and Regulatory Factors Influence Adoption of Cardiac Technologies? Result From the TECH Project**

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The TECH research network collected patient-level data on three procedures for treatment of heart attack patients, (catheterization, coronary artery by-pass grafts and percutaneous transluminal coronary angioplasty), for seventeen countries over an eighteen year period to examine the impact of economic and institutional factors on technology adoption. Specific institutional factors are shown to be important to the up-take of these technologies. Health care systems characterized as public contract systems and reimbursement systems have higher adoption rates than public integrated health care systems. Central funding of investments was negatively associated with adoption rates. GDP per capita also has a strong role in initial adoption. The impact of income and institutional characteristics on the utilization rates of these procedures diminishes over time.

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**Could Health Technology Assessment Be a Tool for Assessing New Vaccines?  
The Case of Vaccines For the Human Papilloma Virus (HPV)**

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**Introduction**

Health Technology Assessment (HTA) can represent an innovative and effective approach to supply decision-makers with a valid instrument to better allocate resources also in the field of vaccines. This approach could be of great interest when decision making process involves choices regarding new vaccines. The aim of our study is to produce a HTA report on the vaccine against Human Papilloma Virus (HPV), that best represents the category of new vaccine to introduce in the European Health market.

**Methods**

The authors developed a HTA approach for assessing all the aspect involved in the introduction of vaccines against HPV in a European Country. The report covers the following issues:

- epidemiological evaluation of HPV infection and related pathologies through the consultation of data banks and scientific literature;
- evaluation of health care resources utilisation by people suffering from the infection/related diseases, through the consultation of hospital archives;
- willingness to pay analysis for the prevention of the disease;
- systematic review and meta-analysis of randomised clinical trials on HPV vaccination effectiveness and safety;
- mathematical modelling to predict the reduction of HPV infection incidence within 10-15 years range from starting a vaccination campaign;
- economic evaluation of the vaccination using a cost-effectiveness analysis;
- evaluation of the impact of the vaccination on Health System [organisational aspects, vaccine surveillance, relationship between different decisional levels (national, regional)];
- analysis of the ethical, social (acceptability, availability, accessibility, information) and legislative aspects of vaccination.

**Conclusions**

The use of a formal HTA approach for assessing the introduction of a new vaccine in the health market has the advantage of giving an interdisciplinary approach to the problem, that goes further the simple systematic review and economic evaluation. This tool will be used by Scientific Societies and all Institutions (Health Authorities, Payers and Politicians) in a European setting for taking actions on vaccination strategies, level of reimbursement and implementation processes.

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### **Needs Ssessment for Venous Implants in the Treatment of Chronic Venous Insufficiency (CVI)**

**Introduction:** The primary aim of medical technologies is to improve the health of the potential target group. Before performing technology assessments, the need for each technology should be determined. Venous implants are a novel intervention with a causal therapeutic approach. The need for this intervention should be quantified in an indication-dependent manner.

**Methods:** Needs-based technology assessment is performed to analyse the need and demand for, and the provision of health care services for CVI, and also assesses the potential of an innovative technology to cover the demand gaps in appropriate target groups. For this purpose, methods of epidemiology, effectiveness assessment, health economics, and health care research (service paths, use of services) are applied.

**Results:** All data refer to the German healthcare setting. *Target group defined by the epidemiology of CVI:* age (5% of > 80-year-olds) and congenital blood coagulation disorders (36% of affected patients) are primary risk factors for CVI. Compression therapy in post-thrombotic patients with severe CVI shows little success. The reference group for this new technology is in any case CVI III patients with a low risk of surgical complications (0.4-0.8% of the population). *Target group defined by technological measures:* 50% of patients with post-thrombotic syndrome (PTS) who have primary valve insufficiency (about 2 million people). In daily practice, about 10% of patients with PTS are interested in surgical therapy. For anatomical reasons, half of these patients are not suited for venous valve transplantation. 60% of the remaining half have a functional venous valve in the upper extremity that can be used as a potential transplant. For the other 40% (about 50 000 patients), an alternative to an autologous venous transplant is needed. *Target group defined by economic conditions:* from the perspective of the reimbursers, a further restriction of the target group is conceivable. Providing the service for patients of an employable age (45% of affected patients) limits the target group to 0.03-0.07% of the total population. The technology seems to be cost-effective for the defined target groups, with an incremental cost-effectiveness ratio compared with compression therapy of about 12 000 €/QALY.

**Discussion:** The needs assessment for venous valve implants determined an objective need for the defined target groups. It is the responsibility of the health care system to regulate innovative technologies efficiently in order to prevent the over-, under-, or misdirected provision of services. In this context, needs assessments can make an important contribution even before the development and diffusion of a technology.

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**The Innovative Medicines Initiative (IMI) – A Public-Private Partnership to Benefit Patients and Society, Involving New Technologies and Processes for Medicines Development**

The Innovative Medicines Initiative is a unique pan-European public and private sector collaboration between: patient organisations, universities, hospitals, regulatory authorities as well as small and large biopharmaceutical and healthcare companies. The objective of IMI is to support the faster discovery and development of better medicines.

The Innovative Medicines Initiative will accelerate the discovery and development of more effective innovative medicines with fewer side effects that reach patients faster. The initiative represents a co-ordinated joint public and private partnership to boost Europe's biomedical R&D base, helping to correct the relative under-funding of biomedical R&D in Europe compared to other regions of the world.

**Enhanced European Competitiveness**

- The Innovative Medicines Initiative is important for Europe because it contributes to the European Union's Lisbon objective of building the most competitive and dynamic knowledge-based economy in the world by 2010.
- The Innovative Medicines Initiative is important for Europe because the application of scientific challenges to drug discovery and development are too complex for organisations to address in isolation. Therefore pan-European public and private sector collaboration and co-ordination is essential to ensure that patients benefit from advances in biotechnology, such as the decoding of the human genome.
- The Innovative Medicines Initiative is important for Europe because it helps to secure long-term prosperity for Europe through biotechnology, which the European Union considers to be essential for developing a dynamic and innovative knowledge based economy, anchoring R&D capabilities in Europe.

**Distinct Benefits for Patients, Scientists and Europe**

- Faster discovery and development of better medicines will benefit patients.
- A more attractive professional environment will benefit scientists and help to address the brain-drain.
- The creation of European expertise and know-how in new technologies will help attract new biomedical R&D investment in Europe.
- The creation and support of sustainable competitive advantage for small-medium enterprises (SME), spin-offs and start-ups will help enhance Europe's economy.

**Implementation**

- The European Union and the European Federation of Pharmaceutical Industries and Associations will take joint responsibility for creating and operating a new international not-for-profit organisation based on article 171 of the Treaty establishing the European Community.
- Over 350 senior representatives of: patient organisations, universities, hospitals, regulatory authorities as well as small and large biopharmaceutical companies worked together to produce the Strategic Research Agenda. This document describes recommendations on predicting safety and efficacy of new medicines as well as plans to bridge gaps in knowledge management and in education and training. These are the principal causes of delays in the complex process of developing new medicines. The Strategic Research
- Agenda is also a roadmap to guide the rapid implementation of IMI, it can be found on the IMI web site ([www.imi-europe.org](http://www.imi-europe.org)).
- The European Union's 7th Research Framework Programme will fund academic participants of Public- Private Collaborations and support SMEs, while the biopharmaceutical companies will fund their own contributions to 100%. Other types of organisations can participate in Public-Private Collaborations and will be supported on case-by-case basis e.g. medical charities. With this

transparent structure, public money will be used to exclusively boost the R&D capabilities of the public sector and small biotech companies, not biopharmaceutical companies. The biopharmaceutical industry partners will match the funds from the European Union's 7th Research Framework Programme with R&D resources such as staff, laboratories, materials and clinical research capabilities.

- The proposed contribution from the European Commission to implement the Innovative Medicines Initiative is €1 billion during the period of FP7 (2007-2013). The annual contribution from the EC will start in the range of €100 million and gradually increase to €300 million at the end of the period. This investment will be matched by members of the European Federation of Pharmaceutical Industries and Associations. And create an overall injection of €2 billion of new funding to boost Europe's science base and stimulate the faster discovery and development of better medicines.

#### Next Steps

- As part of the European Union's 7th Research Framework Programme, IMI will be proposed for Joint Technology Initiative status — subject to approval by the European Competitiveness Council in 2007.

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## **Assessing The Empirical Evidence on the Costs and Benefits of Developing New Drugs – A Global Perspective**

In the worldwide debate on progress in medical technology much attention is paid to the issue of creating and developing new drugs, the costs involved in that process, and the extent to which that investment benefits society. These questions are important for health planning and policy, yet some of the answers are surprisingly elusive and much of the evidence advanced proves to be controversial.

It is incontestable that many of the major advances made in medicine during the twentieth century were due to the introduction of new drugs and vaccines, and that during that period the pharmaceutical industry came to play a central role in identifying and producing them. The fact remains however that a very great part of the world's population still has little or no access to modern drugs, that the main obstacles to such access is widely considered to be their excessive cost to poor populations, and that the high costs are commonly attributed to the investment and expense required for effective research and development. If these things are true, then some drastic changes in both policy and technology would seem to be called for if progress is to continue and be accelerated.

Can we measure the *costs of developing a new drug*? In principle it should indeed be possible to calculate, for any newly introduced medicine, the costs that have been incurred in its creation and evolution; the development process is complex but it consists of finite steps that are meticulously recorded as part of the scientific process. It is surprising then to find that even within individual companies where one has sought to make this calculation one encounters doubts and frank contradictions on the matter. If one seeks to be more ambitious and calculate the average discovery and development costs of new drugs in industry as a whole, the puzzles become even more convoluted. As of 2007 one can cite an estimate from one much-quoted source that this average cost is some \$1.8 billion dollars per drug, yet an estimate from another source rates the expense at something less than a million dollars – a twentyfold difference. Both these extreme estimates are certainly incorrect. Some of the problems encountered in making such estimates are technical and administrative, some might be termed political. Commercial secrecy raises massive obstacles, but so does the desire underlying some studies to work towards a particular conclusion. Today there is a real hope that some firm figures for individual products will emerge through the development of a greater degree of transparency than hitherto.

Measuring the *benefit actually conferred* by a new medicinal product is in some cases perfectly feasible, especially where it represents a breakthrough in treating a hitherto untreatable condition. The bulk of the new drugs entering the market do not however fall into this category; some represent no more than the desire of a manufacturer to secure market share even where this entails a new product having no distinct advantage over those already existing; others do nevertheless represent part of a process of incremental improvement by which slow but ultimately useful progress is made.

The rate of progress in new drug development over a number of decades tends to be variable, advances alternating with periods of stagnation, for reasons that are not always clear. Ultimately, however, it will be vital to create instruments with the aid of which the *balance between investment, innovation and health* can be better understood than has until now been the case.

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## **The Contribution of Certification of Breast Centres to the Globalization**

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**Introduction:** The certification system of the "German society for senology" and "German cancer society" has the objective to clearly improve the medical care of female patients. The two specialized societies regard with the certification mainly the fulfilment and conversion of the fixed technical requirements of breast centres in relation with the S3-Guideline. If a breast centre can fulfil these requirements, the certificate is given by the specialized company OnkoZert GmbH, independently of the number of centres already certified in the vicinity.

**Methods:** The set up of the requirements was based upon the research of the national and international guidelines for breast cancer treatment. The requirements of a certified breast centre are settled in „the technical requirements of breast centres“, and are illustrated in the document called "Data Form". Important steps of the research for obtaining these requirements are the following: Infrastructure, the space and machine equipment; First diagnose, operational primary therapy, adjuvant therapies and aftercare; Psychosocial structures/care; Requirements for personnel; Guide lined medical care; Tumour documentation/quality results; Other technical requirements; Budget plan for fulfilment of requirements. In this Data Form, the hospitals in preparation for certification describe in which way and in which measure they can fulfil the technical requirements. Trying to establish the best Data Form, Pilot certifications were made in 4 different clinics from Germany.

**Results:** OnkoZert together with the 2 societies referred to in the Introduction, have established the final variant of the technical requirements of breast centres, after testing the 4 anterior models on the pilot clinics. Until March 2007, there have been 143 breast centres from Germany, Austria, Switzerland and Italy certified. The certificate is valid for 3 years, with a re-audit every year. An audit lasts in average 1-2 days.

**Conclusion:** In a world, where globalisation seems to be the final target, such a standardisation is a starting concept, which can lead the medical care of female patients to a higher level. The German certification model can be extended to the last countries that entered the European Union, especially for Romania, where this organisation type would have a great benefit for the improvement of medical care.

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**Rural Water Supply and Sanitation Situation: Implications for Human Health in Indian Punjab**

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The Punjab Public Health Department has identified water scarcity villages on the basis of existing problems in terms of water qualities, the number of which has steadily increased from 3712 in 1980 to 11849 in 2005. Another related aspect having deep bearing on human health is the sanitation. Standing water in ponds and otherwise, is the place for breeding mosquitoes and fleas and ultimately a cause of cholera, diarrhea, typhoid, malaria etc. The latrines in the rural houses are either constructed in wrong designs or are not constructed at all. This study was, therefore, carried out to meet the objectives (!) To estimate the availability and requirements of drinking water in the rural Punjab, (2) To bring out the problems of disposal of waste water and water related sanitation problems in the area, (3) To examine the willingness of villages governance to contribute to the provision of water supply and sanitation facilities and (4) To analyze the impact of drinking water supply and sanitation facilities on social and economic life of rural Punjab. The socio-economic survey was carried out in 35 villages representative of 11849 water scarcity villages, covering various distinct situations. The 3 tier data were collected with PRA approach i.e. Village level information from key persons, Household information from respondents, Information from village governance regarding their willingness to contribute to the projects. Data pertained to the year 2005-06. The study highlighted the existence of physical impurities especially in canal water used for drinking purpose, causing tooth decay, graying of hair and abdominal pains. Some people in semi-hilly tracts were reported to be suffering from kidney stone. In most of the areas, the common diseases of Malaria and Diarrhea were reported in rainy season. The family size, nearness to the town, caste and occupation were considered as the major determinants of drinking water requirements of the family. The demand for water for household purposes were believed to vary with a number of factors regressed against the total requirements (usage+additional demand in lit/household/day). The results of regression are  $Dt = 4.61 + 295.54 * Sc + 0.35 * Ls + 90.03 * Ap$  ( $R^2 = 0.422^{**}$ ). As may be viewed from the above fitted linear regression equation, % population scheduled caste category (Sc), Livestock number (Ls) and availability of private assured water supply (Ap) in the house were the major determinants of demand for domestic water. The most critical period with respect to the availability of water and its requirements is the summer season. However, no specific derivation was possible regarding variation in the total water usage within areas near the towns and the areas away from town. On the whole, almost all respondents showed inadequacy for one purpose or the other expressed additional water requirement. Another dimension of expansion of dairy enterprise is by increase in yield of animals with the availability of adequate and quality water. Regarding sanitation, 22% families had open type of latrines, 74% had latrines connected with soaking pits and only 4% were having septic tanks constructed for this purpose. The open latrines were totally unhygienic while the soaking pits were polluting the underground water. Most of the men and women had to travel more than 400 meters for this purpose. The involvement of the village governance in the project was considered essential not only in terms of its acceptability but also its willingness to participate, contribute and share the responsibility physically and financially. The village Chiefs was approached. The extent of response varied from village to village depending upon the outlook of governance members, availability of resources and intensity of problems in the area regarding water supply and sanitation. Almost all the panchayats were willing to undertake the responsibility for recovery of the cost from individual households and contribution of land, labour and material.

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**The National Regulation of Pharmaceutical Markets and the Timing of New Drug Launches in Europe**

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We analyze the impact of national pharmaceutical regulation on the launch delay of new chemical entities approved by the EMEA's centralized procedure. We find that direct price control regimes have a significantly negative impact on the launch timing. These results cannot be found when investigating the impact of indirect price controls. Our results show that Germany (65%) has the highest probability of experiencing an early launch, while it is the lowest in southern European countries (18% for Portugal and 19% for Greece). This difference accrues from both price regulation and market attractiveness, since southern European countries generally have lower prices. Due to the possibilities for parallel trade within the EU, pharmaceutical companies, by acting strategically, may further increase launch delays.

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**Can Deficits in Medical Technology Explain the Evolution of the Health Gradient over the Life Cycle?**

Gisela Hostenkamp and Michael Stolpe

Population ageing requires rethinking the regulation of access to new medical technology. To understand the role of imperfect medical technology in reconciling the human capital theory of health demand with the observation of more rapid declines in health among less educated workers, this paper focuses on the health gradient – the positive correlation between household income and health. More specifically, we study the impact of the health gradient on individual retirement behavior, using data from the German Socio-economic Panel (GSOEP).

We first estimate agegroup-specific health gradients and find their slope increases with age, but declines among retired workers. We then estimate a variety of parametric and semi-parametric duration models and find that workers' position relative to the agegroup-specific health gradient has about the same explanatory power as self-assessed health and income together. We argue our method promises better predictions of the long-term impact of policies affecting the health gradient on workers' timing of retirement amid population aging.

We find what really matters, in addition to health, is not income per se, but workers' relative position on the health gradient, defined by the positive correlation of health and income in each agegroup over the life cycle. The lowest 20 percent (or quintile) of workers along the health gradient are approximately 30 percent more likely to retire during any given period of time than the next 20 percent of workers – and almost twice as likely as the average worker among the 60 percent ranked highest.

We conclude that preserving workers' health regardless of their level of education or income will be one of the major tasks for investments in new medical technology and for health policy throughout the 21st century.

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**Balancing Pharmaceutical Innovation and Cost-Effective Medical Treatment in the US**

The patent is the primary means used in the pharmaceutical industry to protect the intellectual property of newly discovered therapeutics, and has traditionally been used to promote innovation in the health care field. However, there is increasing concern over circumstances where such promotion of innovation can negatively affect the public health. Controversies have erupted over whether patents are sought and awarded to protect aspects of medical research that are not truly innovative, are improperly used to manipulate health care costs or limit access to vital treatments, or are extended past their proper termination point, preventing needed discoveries from entering the public domain. One analysis estimated that inappropriate extensions of market exclusivity and underuse of generic alternatives for just three drugs accounted for US\$1.5 billion dollars in excess spending in a government insurance program from 2000-2004. Two primary mechanisms can help enable patents to continue to encourage innovation while avoiding the problems that can emerge from the effect of monopolies on public health. First, the patent regulatory system can be reformed in a number of ways so that patents are not routinely extended past their proper termination point to prevent needed discoveries from entering the public domain. Second, efforts like the Independent Drug Information Service, currently underway in Pennsylvania, promote cost-effective medical treatment including appropriate use of generic drugs.

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**Exploratory Investigational New Drugs (INDs): Will They Work?**

There is a widening gap in the pharmaceutical industry between high growth in research and development (R&D) spending and the slower pace of new drugs entering the market. To continue to innovate successfully, the industry must explore new models of drug development that decrease risks, stabilize costs and improve the prospect of regulatory approval for drugs entering clinical trials. Responding to calls both from the European Agency for the Evaluation of Medical Products (EMA) and the U.S. Food and Drug Administration (FDA), we build upon a previously published model of cost per compound brought to market to examine how incorporating the use of exploratory investigational new drugs (INDs) changes expected drug development cost.

More specifically, we determine necessary conditions to decrease the cost per approved drug if exploratory INDs are incorporated in pharmaceutical R&D prior to Phase I clinical trials. Constrained in terms of both magnitude and duration of drug exposure, exploratory INDs offer the opportunity to test specific hypotheses related to efficacy in humans for substantially less resource investment than traditional Phase I clinical trials. Improving the quality of decisions regarding which drugs to enter into subsequent Phase I clinical trials has the potential to increase rates of drugs successfully completing all clinical phases and receiving regulatory approval—thereby decreasing cost per approved drug.

We developed three models from which we inferred necessary conditions for a cost-minimizing firm to adopt this option. Model 1 includes the cost of microdosing humans for a range of compounds and costs, utilizing comparative statics to show the necessary drug approval rate increase in order for a profit maximizing firm to prefer exploratory IND options over the traditional process. Model 2 examines how clinical Phase I transition rates, conditional on success in the prior phase, change with the number of compounds entered into exploratory trials. Model 3 considers the effect of increased success rates on clinical costs, given a constant number of compounds entering Phase I trials.

Our results show that the exploratory IND model need only contribute a very small increase in the overall success rate to be preferable to the traditional model of drug development. The total cost of the additional information gained from each compound included in exploratory IND trials is dwarfed by the overall cost of drug development, indicating that better decisions to improve the success rate of gaining regulatory marketing approval can be achieved relatively inexpensively. Finally, improving phase success rates will decrease the phase cost per approved drug, given phase costs remain constant. Phase costs will likely also decrease because of better decisions from gained information therefore causing the cost per approved drug to decrease more. Our results suggest that drug development with exploratory INDs can contribute to the probability of success for individual drugs in a drug pipeline. The use of exploratory INDs can reduce both drug development pipeline attrition and overall development costs, addressing the gap between the R&D costs and the pace of drugs entering the market—improving health outcomes and strengthening the pharmaceutical industry.

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**The Role of Health Technology Assessments in Europe's Regulation of Health Technology – Present and Future**

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Health technology Assessment (HTA) informs health care policy and decision making, and does not mandate policies or decisions. Thus, HTA may inform regulatory control measures, and have a defined role in regulation, but is not regulation in itself. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.

**Healthcare technology** is defined as prevention and rehabilitation, vaccines, pharmaceuticals and devices, medical and surgical procedures, and the systems within which health is protected and maintained.

**Technology assessment** in healthcare is a multidisciplinary field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology.

During two decades HTA has gradually been introduced in most of the countries of Europe. Clarity on what it is and the role it can play in healthcare planning is growing.

HTA has diverse roles in Europe which may reflect the healthcare contexts that HTA is informing.

The EU member states, the European Commission and those who do HTA are searching ways of establishing a sustainable collaboration for HTA in Europe based on the current EUnetHTA project.

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**Designing the Financial Tools to Promote Universal Access to AIDS Care**

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We argue that reluctance to invest in drug treatments to fight the AIDS epidemics in developing countries is largely motivated by severe losses occurring from the future albeit uncertain appearance of a curative vaccine. We design a set of securities generating full insurance coverage against such losses, while achieving full risk-sharing with vaccine development agencies. In a general equilibrium framework, we show that those securities are demanded to improve social welfare in developing countries, to increase current investment in treatments and the provision of public goods. Even though designed for AIDS, those securities can also be applied to other epidemics such as Malaria and Tuberculosis.

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### **Comparative Efficiency of Reference Pricing RP on Drugs – From theory to Practice Some Reflections from the Spanish Pharmaceutical Experience**

#### **COMPARATIVE STRATEGIES FOR PRICING DRUGS**

DIFFERENT INTERESTS in the Pharmaceutical Sector in Europe: GOVERNMENTS: Contribution to health/ Drugs accessibility/ Control expenditure/ Innovation, trade, Industrial & employment policies; PHARMA INDUSTRY: Patents/ Profits; EUROPEAN UNION: Free movement of goods/ Competitiveness

#### NEW POWER RELATIONSHIPS IN THE PHARMACEUTICAL SECTOR

- *MANAGED CARE* (HMO TYPE, UNDER PER CAPITA FINANCING AND 'CHARGE-BACK STRATEGIES WITH MANUFACTURERS)
- *PHARMACEUTICAL BENEFIT MANAGEMENT ORGANIZATIONS* (TO MANAGE THE PAYMENT PAPERWORK ON OUT-PATIENT PRESCRIPTION DRUG INSURANCE CLAIMS, USUALLY UNDER RISK TRANSFER)

#### CONTROVERSIES ON PHARMACEUTICAL REGULATION:

ON LICENSING (L), PRICING (P), REIMBURSEMENT (R) AND PRESCRIPTION POLICIES (M),

- a) A CENTRALISED vs. A DECENTRALISED STRATEGY: THE ROLE OF THE CENTRAL STATE
- b) THE REGIONAL DISCRETION IN PHARMACEUTICAL POLICIES (BEING THE FINAL PAYERS OF THE DRUGS BILL)  
...PLUS IN SOME COUNTRIES:
- ...WITHIN A SOCIAL SECURITY CONTEXT WITH SOME ROLE FOR THE NATIONAL INDUSTRIAL (INNOVATIVE?) PHARMACEUTICAL SECTOR...
- ...WITH A PROTECTED DISPENSATION NETWORK OF PHARMACISTS, AS INDEPENDENT PROFESSIONALS CHARGING % MARGINS...
- **TOO MANY VECTORS FOR COST CONTAINMENT PUT IN PLACE:**
- BREAKING THE MONOPSONY: WHO IS HERE HAPPY?
- BREAKING THE DISPENSATION MONOPLY: HOW TO DEAL WITH THE TRANSITION?
- REFERENCE PRICING (AVOIDABLE COPAYMENT OR UNDER THE FORM OF FACE 'TARIFFS' OR YOU ARE DELISTED)
- HIGH PRICES, FROZEN INCREASES, THERAPEUTICAL MINOR INNOVATIONS, DEVOLUTION OF EXCESS OF REVENUES...

#### **SOME MESSO-MACRO GLOBAL BUDGETING TECHNIQUES:**

- THE PHARMACEUTICAL BENEFIT MANAGEMENT COMPANIES EXPERIENCE IN MANAGED CARE: 'VISADOS' (SECOND OPINION), 'FORMULARIES', TREATMENT PROFILES IN MANAGING ILLNESSES EPISODES..
- UNDER CAPITATION IN REGIONAL FINANCCE, REGIONAL HEALTH AUTHORITIES TEND TO FOLLOW HEALTH MAINTENANCE ORGANISATIONS). PRICES ARE SIMILAR BUT NOT PER UNIT COSTS OF DRUGS

## **SOME OTHER MICRO AREAS**

- Competition: ARE PVP MAX PRICES?
- Incentives: THE ROLE OF THE DISPENSER IN DRUG SUBSTITUTION
- Clinical budget holding: CHANGING PRESCRIBING PRACTICES UNDER NEW RISK-TRANSFER SCHEMES TO PROVIDERS

## **ANALYSIS OF THE EFFECTS:**

- CHANGES THAT AFFECT THE AVERAGE RATE OF EXPENDITURE GROWTH (FOR INSTANCE, BEFORE AND AFTER THE INTRODUCTION OF RP);
- A ONCE-FOR-ALL SHIFT REDUCTION WHICH DOES NOT HELP TO CHANGE THE EFFECTIVE RATE OF INCREASE (THE SLOPE);
- PERVERSE CHANGES WHEN A STEP DECREASE IS REPLACED BY AN EVEN HIGHER THAN BEFORE INCREASE IN EXPENDITURE TREND,
- SUCCESSFUL REFORMS WHEN BOTH SHIFT AND SLOPE DECREASES APPEAR AFTER THE CHANGES.

### (...) caveats:

- THE ROLE OF DRUGS MUST BE SEEN IN THE CONTEXT OF THE HEALTH CARE SYSTEM AS A WHOLE
- AND WE NEED TO KEEP IN MIND THAT INCENTIVES FOR DEVELOPING NEW DRUGS ARE ESSENTIAL TO THE LONG TERM PRODUCTIVITY AND EFFICIENCY OF THE ENTIRE HEALTH CARE SYSTEM.

## **BASICS FOR REFERENCE PRICING.**

- A PROCUREMENT POLICY: A SYSTEM WHERE A MONOPSONIST BUYING AGENT DECIDES ON A REIMBURSEMENT PRICE AND THEN THE USER/PATIENT OR INSURER PAYS THE DIFFERENCE IF THE MEDICINE OF CHOICE IS MORE EXPENSIVE
- HOWEVER, RP DIFFERS IN THE DETAILS AND SCOPE
- GERMANY, THE NETHERLANDS, SWEDEN, DENMARK, NEW ZEALAND, POLAND, SLOVENIA, SPAIN, USA, BRITISH COLUMBIA (CANADA), ITALY AND AUSTRALIA, BUT WITH SIGNIFICANT DIFFERENCES.

### – THE BASICS OF RP

- WE CALL PR THE REFERENCE PRICE, PC THE PRICE FACED BY THE CONSUMER, PL THE PRICE CHARGED BY LABORATORIES AND K THE EXISTING COPAYMENT PERCENTAGE
- Case 1: If  $Pl_1 < Pr$ ,  $Pc$  is set at  $kPl_1$ .
- Case 2: If  $Pl_2 > Pr$ ,  $Pc$  is set at  $Pl_2 - Pr + kPr$ .
- The implicit unit subsidy in each case is  $T_1 = (1-k)$  and  $T_2 = (Pl_2 - Pc) / Pl_2 = (Pr - kPl_2) / Pl_2$
- Since  $Pl_1 < Pl_2$  and  $Pl_2 > Pr$ ,  $T_1$  will compare with  $T_2$  according to  $k$  and  $Pr$ . This is, the per product net subsidy is larger when lower is the difference between  $Pr$  and  $Pl_2$ , and lower is the co-payment  $k$ .
- Although a  $k$  parameter depending on  $(Pl_2 - Pr)$  might be postulated too.

## **- CHARACTERISTICS**

- THE THIRD-PARTY PAYER (PUBLIC OR PRIVATE INSURER) DIRECTLY SETS A CEILING (EXERCISING A SORT OF A RELATIVE *MONOPSONY POWER*) TO THE AMOUNT TO REIMBURSE TO THE MANUFACTURER FOR A PRESCRIBED PHARMACEUTICAL PRODUCT.
- RP IS EQUIVALENT TO SETTING A *COPAYMENT* WHICH:
- IMPLIES A *VARIABLE* AMOUNT DEPENDING ON THE PRICE OF THE SELECTED DRUG; AND
- MAY BE *AVOIDABLE* IF IT IS CHOSEN A PRODUCT NOT PRICED ABOVE THE REFERENCE PRICE.

# IDENTICAL REIMBURSEMENT CEILINGS ARE DEFINED BY GROUPS OF PHARMACEUTICAL PRODUCTS. 'CLUSTERS' OF PHARMACEUTICALS ARE DEFINED IN TERMS OF THEIR *INTERCHANGEABILITY*.

- INTERCHANGEABILITY MAY BE INTERPRETED, FROM A MORE TO A LESS RESTRICTIVE SENSE, ACCORDING TO CHEMICAL, PHARMACOLOGICAL OR THERAPEUTIC EQUIVALENCE.
- CLUSTERS MAY OR MAY NOT INCLUDE PATENTED PRODUCTS.
- THE REIMBURSEMENT CEILINGS ARE ESTABLISHED BY THE INSURER USING (ie. THE OBSERVED DOMESTIC PRICES OF THE PRODUCTS INCLUDED *IN THE SAME CLUSTER* OR GROUP).
- THESE REIMBURSEMENT CEILINGS ARE ADJUSTED PERIODICALLY BY A PREVIOUSLY, ANNOUNCED OR NOT, ADJUSTMENT FACTOR. THE CONCEPT OF INTERCHANGEABILITY AND THE CRITERIA TO SELECT THE REFERENCE PRICE ARE REVIEWED AND POSSIBLY CHANGED TOO.
- *RP IMPLIES A REIMBURSEMENT LIMIT RATHER THAN A FINAL MARKET PRICE.*

– **SOME CONTROVERSIAL ISSUES**

• ***THE CONCEPT OF INTERCHANGEABILITY***

- LEVELS: CHEMICAL, PHARMACOLOGICAL AND THERAPEUTIC EQUIVALENCE
- QUESTIONS ON THE HETEROGENEITY IN THE SAME GROUP OF MEDICINES
- DOES THE DEGREE OF POTENTIAL HETEROGENEITY DIFFER BETWEEN LEVELS OF INTERCHANGEABILITY?
- WHAT ARE THE EXPECTED EFFECTS OF HETEROGENEITY IN THE SAME GROUP OF MEDICINES?
- THE DEGREE OF POTENTIAL HETEROGENEITY DIFFERS BETWEEN LEVELS OF INTERCHANGEABILITY.
- FOR LEVELS 2 AND 3, FURTHER HETEROGENEITY PROBLEMS MAY ARISE
- SORTS OF PROBLEMS ARISING FROM HETEROGENEITY BETWEEN CLUSTERING DRUGS (“THE COSTLY CONSEQUENCES OF ASSUMING ALL PATIENTS ARE THE SAME”) PARTICULARLY IMPORTANT IN LEVEL 2 AND 3 GROUPS.
- IT APPEARS THAT *RP* PRODUCED *SHORT TERM* REDUCTIONS IN INSURER'S *EXPENDITURE*. *RP* DOES NOT RESULT IN IMPORTANT *LONG TERM* SAVINGS.
- THE *PRICE* OF PRODUCTS COVERED BY *RP* TEND TO DECREASE. INITIAL PRICE REDUCTIONS ARE REPORTED IN ALL COUNTRIES WHICH INTRODUCED THIS MECHANISM.
- PRICE AND MARKET SHARE OF *NON COVERED PRODUCTS* INCREASED NOTABLY. GENERALLY, PHARMACEUTICAL FIRMS INCREASED THE PRICES OF PRODUCTS NOT DIRECTLY AFFECTED BY *RP*.
- WHEN THE *GENERIC* SUBSTITUTION RATE WAS HIGHER BEFORE IMPLEMENTING REFERENCE PRICING, THE EFFECT OF *RP* ON *GENERIC* MARKET SHARE HAS BEEN MINIMAL, ALTHOUGH IN SOME COUNTRIES AS IN GERMANY, A MODERATE INCREASE IN THE SHARE OF *GENERIC*S IS OBSERVED
- AT ANY RATE, THERE EXISTS *DIFFERENT TYPES OF REFERENCE PRICE SYSTEMS*:
- DIFFERENCES IN THEIR PRODUCT COVERAGE: LEVEL OF EQUIVALENCE (CHEMICAL, PHARMACOLOGICAL AND THERAPEUTIC) AND INCLUSION OR EXCLUSION OF PATENTED DRUGS.

**ADVANTAGES AND DISADVANTAGES**

- MANUFACTURERS REMAIN FREE TO SET ANY PRICE THEY WISH. PHARMACEUTICAL COMPANIES MAY INCREASE THEIR MARKET SHARE IN A FULLY TRANSPARENT CONTEXT.
- *RP* DOES NOT SET LEGAL LIMITATIONS ON THE FREEDOM OF THE DOCTOR TO PRESCRIBE DRUGS, SINCE ALL DRUGS ARE AVAILABLE (IN CONTRAST WITH POSITIVE AND NEGATIVE LISTS).
- POTENTIAL REDUCTIONS IN PHARMACEUTICAL EXPENDITURE (THE COST CONTAINMENT EFFECT) MAY BE ACHIEVED WITHOUT ANY SACRIFICE IN EFFECTIVENESS (*RP* HENCEFORTH WILL IMPROVE COST-EFFECTIVENESS)
- REFERENCE PRICING MAY FAIL TO CONTAIN PHARMACEUTICAL SPENDING.
- (A) *RP* CAN ONLY BE APPLIED TO A NARROW PROPORTION OF THE PHARMACEUTICAL MARKET, AND USUALLY NOT TO THE DRIVING FACTOR OF THE DRUGS BILL GROWTH.

- (B) FIRMS MAY MINIMIZE THE EFFECT OF *RP* ON TOTAL PHARMACEUTICAL REVENUES: ATTEMPTING TO RECOVER LOSSES BY INCREASING PRICES OF THOSE NON COVERED BY *RP*. *RP* STIMULATES THE INDUSTRY TO MAKE A MAJOR EFFORT IN ORDER TO PROMOTE DRUGS THAT ARE NOT UNDER THE SCHEME.
- (C) SAVINGS IN PHARMACEUTICAL EXPENDITURE UNDER *RP* ARE BASICALLY ACHIEVED AT THE EXPENSE OF INCREASED EXPENDITURES IN THE UTILIZATION OF OTHER HEALTH CARE SERVICES, AS HIGHER HOSPITAL ADMISSION RATES OR HIGHER RATES OF REFERRAL TO OTHER PHYSICIANS (HIGHER COSTS ELSEWHERE IN THE HEALTH SYSTEM).

...*RP* IS ALSO QUESTIONED BECAUSE OF ITS INSENSITIVITY TO DIFFERENCES IN THE CLINICAL PROFILE OF DRUGS THE HETEROGENEITY PROBLEM IS PRESENT IN EQUIVALENCE LEVEL 2 AND 3.

...FINALLY, *RP* IS ALSO CONTENTIOUS BECAUSE OF THE POSSIBLE NEGATIVE EFFECTS ON EFFICIENCY AND ON R&D.: WHAT DOES IT ADD TO A WELL DEVELOPPED COMPETITIVE MARKET FOR GENERICS?

#### **Addenda: The SPANISH *RP* settings:**

- According to 1999's Royal Decree, reference prices were established from a weighted average by the sales of the public prices sales of the minimum amount of smaller price presentations, necessary to reach a market share in 20% units.
- If the difference between the calculated price and the highest one in the group was less than a 15%, the reference price resulted in reducing the highest price in a 10% (with a 10% saving guaranteed)
- If the difference between the calculation and the highest one was more than a 50%, the reference price was recalculated.
- The generic speciality with a lowest price in an homogeneous group was established as the price's minimum.
- When the medical prescription overcome the amount of the reference price, the pharmacist will not be obliged to a substitution when no generic pharmaceutical speciality that fulfils the interchangeability requirements demanded exist.
- When no substitution is due to the inexistence of a generic, the pharmacist will have to deliver the prescribed speciality with the reference price, price on which the beneficiary will have to make the contribution that corresponds to him. In that case, the laboratory will have to pay the difference between the sale price of authorized laboratory and the one that corresponds with the reference price.
- A former modification (2003) made for not accounting anymore for the market quota, choosing to consider just the arithmetic average rate of the three costs/ treatment/day minor for each form of administration.
- The new proposal (2007) means a new modification that adds the requirement that the three selected presentations to fix the price of reference will have to belong to three different enterprise groups.
- The reformulation of the reference prices' system has suppressed the exceptions to the substitution by the pharmacist of the speciality prescribed by the doctor with a greater price than the reference one.

...as a result, if the patient decides to follow the prescription of his doctor, he will have to assume the totality of the brand price and not the difference between his sale price to the public and the price of reference, as in the past, unless a cheapest group's generic one does not exist: as said, this is equivalent to an exclusion de facto of the public financing of the brand specialities with prices above the price of reference.

- So far, it does not seem that the new *RP* system is helping to the creation of a true market of generics (the market is stuck in a 4%) and no new incoming companies are appearing in this section of business but the large pharmaceutical Companies, offering its "brand" generics with prices near the reference one, according to the regulated calculation.

(in principle to protect this market, no product with a price under 2 € is computed for the price calculation).

#### **CONCLUDING REMARKS**

- *RP*- EFFECTS, CONTEXT DEPENDENT...
- IT IS NOT SO MUCH THE IDEA IN ITSELF BUT HOW THIS IS IMPLEMENTED: PUBLIC PROCUREMENT WITH SOME POLITICAL DISCRETION, INCENTIVES TO THE AGENTS, CONTROVERTED MEDICAL BIOEQUIVALENCES
- *RP*- MAY MEAN EQUITY AND EFFICIENCY AT THE SAME TIME
- SOME CAVEATS ON THE EFFECTS ON CREATING A FULLY COMPETITIVE MARKET FOR GENERICS AND ON R&D

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**HTA-Methodology For Innovative Healthcare Technologies – The Inno-HTA Project**

Dagmar Luehmann for the Inno-HTA-Consortium\*

High expectations are related to innovations in healthcare with respect to improving treatment outcomes, saving healthcare expenditures and generating employment. Decisions about clinical development, market introduction, application in patients etc. have to be supported by scientific evidence. However, regarding emerging health technologies, the potentials of HTA are not fully exploited yet. In 'classical' HTA the innovation component is nearly totally missing. Thus, advances in medical technologies in their early states are not sufficiently utilized.

The EU-funded project "Inno-HTA" aims at helping close the gap between the development of new technologies and their application. A generic methodology for the evaluation of health innovations is developed that expands the focus of HTA to include aspects of the technology as such, its scientific foundation, potentials, implementation and effects on society as well as implications of adoption or non-adoption.

The methodology includes a broad structured consensus process with producers and users of HTA reports. Main result will be an internationally agreed set of indicators for the assessment of health innovations. It will support the use of HTA where 'classical' HTA is not yet applicable. The project is coordinated by the Fraunhofer Institute Systems and Innovation Research, Karlsruhe, Germany; other participants include HTA agencies, scientific experts for the evaluation of emerging health technologies as well as for 'classical' HTA, and health economists. The consortium will be supported by a board of advisors.

The presentation will inform about the methodology and discuss first results on indicators that are actually used to evaluate healthcare innovations.

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**Diffusion of Diagnostic Medical Devices and Policy Implications in India**

**Objectives:** To describe the diffusion of advanced diagnostic devices in India and to assess implications for efficiency in resource use and equity.

**Methods:** Commodity-level import statistics, household survey data and interviews with medical device sellers were used to assess the spread of diagnostic devices. Published qualitative evidence, case studies of diagnostic service providers and cross-country analyses were used for analyzing the reasons underlying the spread of medical devices in India. Case studies of public and private providers and data from 150 hospitals in one Indian state were used to assess efficiency in resource use and the distributive impacts of diagnostic devices.

**Results:** High-end medical device inflows rose during the 1990s with both supply- and demand-side factors influencing this trend. Although our results suggest that the overall quantity of advanced diagnostics in India is not excessive, there is some evidence of inefficiency in public facilities and possibly unethical practices in private diagnostic facilities. The unequal geographical distribution of MRI facilities, coupled with inefficient use of medical devices in public facilities suggests inequality in access.

**Conclusions:** The paper points to major regulatory gaps and health system inefficiencies and suggests ways in which these gaps can be addressed.

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**Managing Medical Technology: The Medical Innovation Chain in Australia**

Beginning with the organisation of medical scientific research and going through to the commercialisation of research results and their adoption in medical facilities, the paper discusses the innovation chain within the field of medical technology in Australia. The chain is taken as including especially the development of medical technologies within Australia but also considers the adoption of technologies developed overseas. The paper highlights the points at which regulation of different kinds, or the lack of appropriate regulation in some cases, is a critical component of the chain and indicates the implications of particular organisational practices and policy directions at these points. The paper argues that because the innovation chain, which includes medical user facilities, is not considered as a whole by policymakers the regulatory framework is not coherent and in crucial areas does not take sufficient account of the particularities of the Australian medical, organisational and economic context. In particular, the paper shows how both separation of funding for medical technology research from the directions taken by policymakers within State and federal Departments of Health and Departments of Industry and the separation of health responsibilities as between State and federal authorities are still causes of friction in the development and adoption of new medical technologies.

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**A Model for National System of Health Care Technology Selection and Use in Iran****The issue**

A large number of scarce financial resources of health is allocated to medical equipment expenditures while the effective use of existing equipment and appropriate selection and use of new health equipments is under question. Due to health reform program interest to study Iranian system for the selection and use of medical equipments and design a system for the selection and use of appropriate equipment in the health system, the Iranian health technology assessment group analyzed the current situation and designed the improved model of medical equipment management in Iran.

**Objectives**

To review and analyze current system for the selection and use of medical equipments in terms of policy making & planning, financing, selection and use administrative and legal dimensions and methods to design an improved model of medical equipment appropriate selection and use in Iran.

**Methods**

The study is based on the SSADM structured System Analysis and Design methodology through exploring, confirming and completing interviews with expert group of medical equipment management from all stakeholder organizations in Iran. The report also was enriched with a broad view of international literature and international consultants ideas added to data from internal experts. A structured questionnaire focused on the basic issues of medical equipment management was utilized for data collection and its findings were analyzed after confirming and complementary interviews according to SSADM methodology. To clarify current organizational arrangement and relationships the results of this phase of study were translated to DFDs data flow diagrams & ERDs Entity Relationship Diagrams. Then we outlined the optimized system of selection and use of medical equipment based on WHO documents, literature search results on health technology assessment and management issues in the world and international consultants recommendations. After a systemic managerial analysis and comparing the existing system with ideals, and seeking stakeholder attitudes around outlined system, we designed improved DFDs and ERDs with a focusing approach on process-based structuring. In this approach the different less-valued committed duties in the field of medical equipment management like administrative process of licensing will be replaced by high-valued process like need assessment, technology assessment and maintenance by expert's contribution. Also we defined conceptual perspective, organizational structure, infrastructures, prerequisites of model and new relationships in an integrated national model.

**Results:**

This report details the current situation of medical equipment selection and use system in Iran and presents these aspects that require immediate attention which is considered in the systemic designed model:

- Health technology/medical equipment policies should be an integral part of health policy. The fact that the best decisions of equipment policies and plans can be formed when health managers develop health system priorities, essential care package and standard setting of technologies in the strategic and operational health plans.
- The current organizational approach and structure of health technology/equipment management system are confused with variety of non defined duties with less value for increasing efficiency and productivity in a very complex relationships. These should be replaced by important effective process like assessment of population and health program's needs to technologies/equipments and selection of best available alternatives in terms of safety, effectiveness and economical dimensions and compatibility with Iranian health system.
- A network activities of health technology/health equipment assessment should be established by arranging of elementary activities on technology pre-assessment in limited hospitals and universities and mini HTA in well developed universities and hospitals and medical equipment center of MOH and comprehensive HTA in a national HTA agency. The level of permitted decision making depends on the price of technology and acuteness of care and its impacts on the health system outcomes.

- An integrated ration who met the need to appropriate technologies dealing with strategic plans and priorities of health system, technology assessment views and effective allocation pattern.
- A model for stratification of health organizations and defining their role in the new system of assessing medical equipment requests and needs is suggested.

Conclusively, the report presents a systematic analysis of current situation on the “medical equipment selection and use system” in three levels of MOH Medical equipment office, Medical universities and hospitals and so principles of optimized model and finally recommends an improved national model as it is detailed with improved diagrams including DFDs and ERDs & policy, organizational, administrative and legal infrastructures and necessities in the text.

#### Recommendations:

- Build required capacity which is needed for application of new model
  - Define essential health care package in each level
  - Detect standard health technology who meets essential care
  - Develop real strategic and operational plans clarifying required technologies
  - Design inventory and preventive maintenance soft wares
  - Train policymakers, managers & staff to be familiar with new approach and be capable of producing qualified reliable assessment of technology/health equipment or its implementing.
- Support Health technology assessment activities and institutionalize the need to assess health technologies/equipments before their acceptance and acquisition in health system

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**TRIPS – Issues, Impact and the Way Forward for Developing Countries, Including India**

The Conclusion of the Uruguay Round(UR) and the signing of the agreement on Trade Related Aspects of Intellectual Property Rights(TRIPS) by member nations under the multilateral trade negotiations is a major landmark in the discipline and development of international law. However, many member countries of the WTO are faced with many difficult questions in defining their respective national intellectual property strategy and policy and designing intellectual property rights legislation in conformity with those policies and requirements of the TRIPS Agreement.

The extent of protection and enforcement of intellectual property rights varied widely around the world and these differences became a source of tension in international economic relations. At the same time, they have been recognized as a development issue. It seems that TRIPS agreement is an attempt to narrow the gaps in the way these rights are protected around the world, and to bring them under common international rules. The Ministerial Meeting in Doha issued a Declaration, which stressed the need for TRIPS Agreement.

The main objective of this policy draft is to provide better understanding of the economics and content of the TRIPS agreement and suggest the way forward to those countries who are in the process of designing the fine print of the IPR code and also for those which have already adopted legislation in this area. This draft has reviewed the implications of the TRIPS agreement based on the issues raised by the developing countries. It provides an overview of the relationship of intellectual property rights with various development dimensions of the economy. The policy draft also analyses provisions on copyright and related rights in TRIPS and in the relevant provisions in the Berne Convention and discusses the new World Intellectual Property Organization(WIPO) treaties and the unresolved issues on databases and audiovisual works. The policy draft also discusses the patent regime of India and examines the impact of the new TRIPS regime beyond 2005.

Contrary to popular perceptions many developing countries were already in compliance with many of the specific provisions of TRIPS. For example,many developing countries have a long tradition of protecting copyright,having continued and even further strengthened national laws instituted in the late nineteenth century. However,in certain areas they are unlikely to give up limited flexibility available in TRIPS to alleviate any perceived ill effects of such protection or to balance the interest of third parties.

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**Why Licensing Authorities Need to Consider the Net Value of New Drugs – Addressing the Tension Between Licensing and Reimbursement**

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Pharmaceutical regulators and health care reimbursement authorities operate in different intellectual paradigms and adopt very different decision rules. This leads to situations where drugs that have been approved for use by licensing authorities are not made available to patients because the judgement of the reimbursement authorities is that the cost of therapies is greater than the health gain they produce. This in turn creates great uncertainty for pharmaceutical companies attempting to plan their investment in research and development, as licensing is no longer a guarantee of market access. In this paper we propose that it would be consistent with the objectives of pharmaceutical regulators to utilise the Net Benefit Framework of reimbursement authorities to identify those therapies that should be subject to priority review, that it is feasible to do so and that this would have a number of positive effects including reducing the tension between regulatory and reimbursement authorities, produce downward pressures on the cost of drug development and inject greater certainty in to the pharmaceutical industry's investment planning environment.

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**The National Regulation of Pharmaceutical Markets and the Timing of New Drug Launches in Europe**

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We analyze the impact of national pharmaceutical regulation on the launch delay of new chemical entities approved by the EMEA's centralized procedure. We find that direct price control regimes have a significantly negative impact on the launch timing. These results cannot be found when investigating the impact of indirect price controls. Our results show that Germany (65%) has the highest probability of experiencing an early launch, while it is the lowest in southern European countries (18% for Portugal and 19% for Greece). This difference accrues from both price regulation and market attractiveness, since southern European countries generally have lower prices. Due to the possibilities for parallel trade within the EU, pharmaceutical companies, by acting strategically, may further increase launch delays.

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**Color Visualization of Blood Cells as Result Interaction of Visible Light with Two Layer System Cell-Substrate**

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Introduction: Color visualization are widely spread in biological and medical studies of difference samples. But for this purpose need special treatment of samples under expensive chemical prepares. This procedure is changing native structure biomedical sample and lead to distorted its image under microscope. Other method for color visualization is connected with using interference microscope based on transmission of white light through bio-medical sample. But this microscope have complicated additional and expensive optical system for getting two coherent light.

Materials & Methods: To get most cheap and convenient method color visualization human tissue cells, (blood cells, urine, saliva and other physiological liquids) without any chemical treatment and using expensive interference microscope we proposed new method based on using ordinary optical microscope and special substrate on what we put the investigating sample. Measurements has been performed for human tissue, blood cells, saliva and urine for health perfect and for difference stage cancer patients. Method based on light interference reflected from sample surface and interface cell-substrate.

Results: Developed new technique for fast in real time regime to get color image of human blood cells without any chemical treatment. This method let us to determine chemical compounds of blood cells by comparison this color image with calibrate color map.

Discussion and conclusion: We offer new method to get two coherent light based on biomedical sample reflection and special no transparence supporter reflection of the white light. In result we can see color interference picture of the biomedical sample under ordinary optical microscope without using any chemical treatment and expensive interference microscope. This method may be used in medical laboratory, hospitals, research centers and individual users for fast public and self diagnostics.

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**Adoption of Health Technology for Controlling the High Growth Rate of Population in India: An Explorative Study**

India is one of the second largest populated country in the world since long back. Though in the past especially before 1940 the growth rate of population was not high because of several reasons, after wards the growth rate of population in India was increased like anything especially due to the drastic reduction of mortality rate which is the effect of advanced science and medicine. But simultaneously the rate of fertility was high which caused the high growth of total population in India. For this reason India is the first country which intervene in the individuals life for targeting to reduce the rate of fertility among the currently married couples in the age group 15 to 49 in the name of family planning programme for aiming to control the high growth rate of population. With the above background it creates some research anxiety to study the real health technology adopted for controlling the high growth rate of population in India. The main objective of this paper is to examine the adopted health technology for controlling the high growth of population in India since 1950s. After wards an attempt is made to explore the various policies adopted by the government of India for controlling the high growth rate of population since 1950s till today. The paper utilizes the secondary data for achieving the above objectives through government of India publications, census of India in various years, and available health related data from other sources like national family health survey and reproductive and child health survey in various years. For the analysis the paper used the time series data for trend fitting, some descriptive statistics, as well as some relevant test statistics. In spite of this the paper makes an endeavor to find, is there any significant relationship with the adopted health technology for controlling the high growth rate of population in India. From the analysis it is found that the adoption of health technology for controlling the high growth rate of population played an important role to make the family planning programme successful, especially the adoption of technology such as pills, IUD insertions, condoms and others. In spite of this we found the rate of availability and the demand for technology for controlling the high growth rate of population with respect to sex and residence. The paper concludes with suitable policy suggestions from the ethical point of view.

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**Economic Effects of German-Style Reference Pricing**

The reference pricing (RP) policy for drugs is among the means used by public authorities to reduce the costs of public insurance. Formally instituted for the first time in 1989 in Germany, other countries across the world also adopted it to varying degrees since then (the Netherlands, New Zealand, France, Italy, Spain, Denmark, Australia and the Canadian province of British Columbia, among others).

Reference pricing presents different economic effects.

On the one hand, in the health insurance field, by emphasizing cost reduction, RP provides savings for funds related to the use of medication. However, such a policy also has its drawbacks. For example, it imposes on the insured a limited mandatory coverage for certain drugs, and it relies on the use of a bureaucratic classification of groups of drugs that are considered substitutable even if patients may not see it in the same light.

On the other hand, German-style RP represents a reimbursement policy which has an indirect effect on pharmaceutical innovation by discriminating against new medicines. Drugs representing incremental innovations – which are bureaucratically classified in the same classes with old and generic drugs – are especially penalised. Such bureaucratic classification tend however to disregard the fact that pharmaceutical innovation – like the process of innovation in other fields – remains by its nature an incremental process and its results have to be evaluated by the beneficiaries of new drugs, i.e. the patient / insured. German-style RP thus ends up also penalising the process of innovation itself without giving any opportunity to these beneficiaries to approve or disapprove such a policy.

In order to achieve optimal spending on drugs – that patients are willing to pay directly from their pockets or indirectly through their insurers, recognising consequently the potential added value of new drugs – ultimately public health insurance monopolies would have to be called into question.

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**The Strategy Methodological Approach of International Pharmaceutical and Health Technology Development**

The economic strategy decision in the sphere of medicine and pharmaceutical market must be directed to the unification of international standards and include using the global approach to the control of enterprise activity. But, nowadays trends of economical development and different standards of living in many countries are prevented from application of this conception. The strategy system of pharmaceutical and health technology development needs to be improved. From our point of view, the methodological approach of selection a suitable strategy for medical and pharmaceutical enterprise in each geographic region includes three main stages:

1. formalization choice of international market segment, according to the macro indexes;
2. forming the enterprise competitive principles based on a map of strategic groups;
3. determining the enterprise position with the learning of cross-culture differences and stereotypes of using medical and pharmaceutical products in different countries.

The first stage of proposed methodological approach can be realized by building the nine segments matrix. It is formed with the help of the next system indexes: Ginny coefficient and index of human development. The first index displays uniformity of distribution of gross income, which allows to define the price policy in any country. On the other hand, index of human development that reflects the quality and lifetime in the countries, defines the demand on quality medical and pharmaceutical products. Thus, placing countries in this matrix allows to identify the progressive segments for medical and pharmaceutical enterprises development in international market on the basis of price and quality of the products of these enterprises.

On the next stage of this method, it is necessary to analyze the competitive principles of enterprise on a selected international market segment and form the successful strategy of its development in conditions of unsteady external environment.

For further success of international management decisions, on the third stage of the method it is necessary to adapt the product to the cultural features of national market on the basis of existing stereotypes of product using.

The use of the proposed methods allows to make the motivation choice of adaptive competitive strategy on the basis of formalization approach, directed to long term development of medical and pharmaceutical enterprises in the sphere of international economic affairs.

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**Keeping Track of Rapidly Developing Technologies: The French Experience**

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Decision-makers are under increasing pressure to adopt more flexible marketing and reimbursement rules for innovative health technologies. While fast-tracking procedures may ensure earlier access to technological progress, they also contribute towards increasing uncertainty at the time the decision is made, regarding both its medical and financial consequences. Decision-makers are thus faced with difficult trade-offs which high quality, timely assessments and careful monitoring can help resolve.

This article analyses some of the pragmatic solutions adopted in France to monitor the introduction of rapidly developing technologies, in the light of some of the relevant concepts of industrial economics. The first trade-off is to reduce the probability of taking inappropriate decisions without excessively delaying access to the new technology. The second is to reward truly innovative technologies, while keeping within the Nation's health budget.

Having specified the main trade-offs which are common to most developed countries, we describe the standard monitoring procedure for new technologies in France and then turn to the recent experience with facilitating and conditional mechanisms for innovative technologies. Several fast-track devices are used to tackle these trade-offs: authorisations for temporary use, temporary treatment protocols, fast-track procedures for a drug "deemed *a priori* innovative", conditional coverage with follow-up studies and finally risk sharing.

This review shows that the pragmatic solutions adopted in France could be of relevance to other developed countries inasmuch as the challenges identified are shared by most. Coordination in the actual monitoring phase could also be fruitfully considered.

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**Intellectual Property Rights and Other Policy Issues in the Development of Biotechnology**

Advances in biotechnology and genetics offer much promise for sustainable growth and development of economies and for society more broadly. Genetic innovations already play an important role in the health field. However, efforts need to be made to ensure that these advances deriving from a better understanding of genetics are made available to those who stand to benefit, both in developing and developed countries. To achieve this objective, new approaches must be considered. The OECD is carrying out work with respect to stimulating novel approaches, especially in respect of biotechnology, health and innovation as well as intellectual property.

With respect to biotechnology, health and innovation, two projects are illustrative. One project focuses on emerging research models, which will examine the opportunities of pre-competitive knowledge markets, and the other project will focus on accelerating drug development for infectious diseases. With respect to intellectual property (IP), the challenge is to develop a more nuanced and balanced approach by carrying out work that will stimulate the use and sharing of intellectual property so as to foster innovation and diffusion, and facilitate access to inventions, technology, and know-how. In order to address concerns and to ensure better access and diffusion of knowledge, technology, products and services, to foster innovation and to stimulate R&D, OECD Council adopted the *Guidelines for the Licensing of Genetic Inventions*. They offer principles and best practices for the licensing of IP rights that relate to genetic inventions used for the purpose of human health care. Similarly, through the Collaborative Mechanisms initiative, work is being carried out on factors and mechanisms for encouraging collaboration with respect to IP amongst diverse interests in order to stimulate innovation, foster R&D and promote access to and diffusion of technology and information.

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**Cutting the Edge – Male Circumcision for HIV Prevention as an Example of Health Technology Transfer between Countries, Cultures and Contexts**

Male Circumcision (MC) is today a proven intervention which reduces the probability of transmission of HIV from infected women to men by up to 60%. Three controlled trials (in South Africa, Kenya and Uganda) with more than 10,000 participants provided the clear cut evidence, supporting previous observational and meta-analysis studies of recent years. The results published in July 2005 and December 2006 led to the development of a UN Work-plan on MC and HIV.

Countries most affected by HIV/AIDS need now to develop evidence-based policies, programs and training; and be guided by the international community how to either scale-up or role-out male circumcision services. This is one of most diverse policy debates in the field of public health and the area of medical decision making.

Managing large-scale adult male circumcision services is required if we are to be able to make good use of the promising intervention and try to reverse the devastating AIDS pandemic in Africa. Very few countries have meaningful experience with hospital/clinic-based MC for adults.

A decade long experience in adult MC recruits attention in Israel. Over 20,000 MC operations on adults are documented, mostly performed voluntarily on Jewish migrants from Eastern Europe. This unique experience is now being developed and packaged for transfer to low-income countries facing a dramatic AIDS epidemic with limited percentages of MC.

The paper will present options for MC technology transfer to Africa, in view of current challenges in scaling up or rolling out MC services for HIV prevention.

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**Transferability of Economic Evaluations of Medical Devices: An Example of the Use of Fibrin Tissue Sealant in Orthopaedic Surgery**

Lotte Steuten, Health Economics Research Group, Brunel University, UK; Laura Vallejo-Torres, Health Economics Research Group, Brunel University, UK; Martin Buxton (Prof), Health Economics Research Group, Brunel University, UK.

**Rationale:** Economic evaluation is increasingly needed to support the adoption of new medical devices, and in some countries the evaluation must have been published if it is to be used for marketing purposes. Cost and time constraints typically preclude the possibility of undertaking formal studies for every market, and decision-makers frequently face the question of whether results from one country can reasonably be transferred to another.

**Objectives:** This paper explores a methodological approach to support decision-makers in the context of transferring results of economic evaluations to other settings by producing/publishing an analysis addressing transferability that would be relevant to all or many markets/countries. We illustrate the idea in the context of a product for orthopaedic surgery (i.e. fibrin tissue sealant) which has been subjected to a cost-analysis in the UK, but for which the results need to be transferred to other European countries (France, Italy and Germany).

**Methods:** We retain the methods and data that are applicable to other countries and identify the factors that limit the transferability of study results. These factors are categorised, and necessary adjustments to deal with each particular issue are proposed in this paper.

**Results:** The factors most relevant to the transferability of these results to other European countries are the costing approach for direct costs, and the absolute and relative prices in healthcare; and to a minor extent, the evaluation perspective, practice variation (e.g. hospital discharge policy, blood transfusion procedures), and the availability of the technology in public and/or private hospitals as determined by national medical device regulation and adoption policies.

**Discussion and conclusion:** Based on the analysis, it is proposed to substitute the direct cost parameters for which the outcomes of the cost-analysis were shown to be most sensitive, being 1) cost of surgery, 2) cost of a hospital inpatient day, and 3) cost of blood transfusion; and the absolute price of the fibrin sealant per dose applied, with country-specific data. Differences in evaluation perspective are handled by selectively including relevant parameters to reflect the appropriate perspective. Practice variation and availability of technology are dealt with in a two step approach. First, the level of correspondence regarding these issues between the UK and the country at stake should be assessed. If correspondence is good, the original methods and data can be retained. If it is poor, the variability in the affected parameters should be estimated. Multivariate sensitivity analysis is proposed to provide insight into the potential impact of each of these elements to the transferability of the results of the economic evaluation.

[Data illustrating this approach will be available at the time of the conference]

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**Optimal Risk Sharing Between Developers and Payers for New Medical Technologies**

Adrian Towse MA MPhil has been Director of the Office of Health Economics since 1992. His interests include the use of "risk-sharing" arrangements between health care payers and pharmaceutical companies to manage the introduction of new health technologies; the economics of pharmacogenetics for health care payers and for the pharmaceutical industry; economic issues around the use of public private partnerships for the development of treatments for less developed country diseases; and the economics of medical negligence – incentive properties and costs of 'no fault' versus reformed tort procedures.

## **Velázquez, Adriana**

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## **Health Technology Adoption in Latin America – Institutions and Policies**

Latin America is undergoing an important development towards the regulation, evaluation, assessment, management and appropriate use of Health Technologies in the XXI Century.

It includes 33 countries, 543,248,000 inhabitants, and 16,566 second and third level hospitals, out of which the 44.5% are public institutions.

Considering health technologies as “the drugs, equipment and medical devices, medical and surgical procedures, and the organizational models and support systems,” the countries can be divided – depending on their regulation, adoption and management of technology – in three main groups. The first group has regulatory agencies in their government and these aim to increase the quality of health services by applying regulation policies for medical devices and medicines. The countries in the second group do not necessarily have dedicated regulation agencies of their own, but take into consideration policies offered by the first group countries. And finally there are some countries which really lack all the regulation infrastructure, do not have biomedical engineers in their health ministries and are striving towards a better health technology adoption policy to enhance safe and quality use of medical devices and drugs.

Inside every country, the strongest part of the regulation process is performed by the public institutions. The private ones have a different way in which they select mainly what they need, and just about a 10% of them does enhance to have a process of health technology evaluation.

In the first group of countries, where Argentina, Brazil, Chile, Colombia, Cuba and México belong, their regulatory agencies cooperate between them and have assisted to a regulatory forum in Mexico in 2006 and in Brazil in 2007: ANMAT, ANVISA, ISP, INVIMA, CECMED, and COFEPRIS. Just following this experiences, are Venezuela, Uruguay, Perú, Panamá, Costa Rica and Bolivia.

Most of the large volume of medical devices goes through regulation agencies, depending on the requisites involved, some are more indulgent. And then the next step is how it is decided to purchase that equipment by the public institution.

The Health Technology Assessment Policy is just starting to develop in some of the health ministries of this list of countries, which in turn are promoting the use of Health Technology Assessment in the rest of Latin America to provide recommendations for prioritization or acquisition of health technologies. Such has been the work of PAHO, PACME with APEC, OECD, WHO, ACCE, HTAI, INAHTA, CORAL, and others who promote this policies in Latin America.

Much is yet to be done, and specially in the harmonization of nomenclature, of GMP, of technovigilance with the rest of the international area, because the main task is to deliver health with safe, efficient, cost effective health technology increasing the quality the advancement and the excellence in health care provision, and so we should do everything possible to motivate it, for the well being of our societies.

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**Legal Aspects in the Assessment of New Medical Technologies in Belgium**

When new medical technologies enter the market, there is often uncertainty about the added value for the patient and for society, hampering well considered decision making about reimbursement. Current Belgian legislation already offered opportunities for the managed uptake of possibly innovative emerging implants. However, it has also some shortcomings such as the lack of a clear research design, rendering the scientific evaluation of clinical effectiveness, cost-effectiveness and patient- or organisational issues more difficult. Against this background a new procedure was elaborated by the Belgian health insurance institute and the Belgian Health Care Knowledge Centre.

**Vogt, William B.**

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**Is Drug Coverage a Free Lunch? Cross-Price Elasticities and the Design of Prescription Drug Benefits**

Martin Gaynor, Jian Li, and William B. Vogt

Recently, many US employers have adopted less generous prescription drug benefits. In addition, the U.S. began to offer prescription drug insurance to approximately 42 million Medicare beneficiaries in 2006. We use data on individual health insurance claims and benefit data from 1997-2003 to study the effects of changing consumers' co-payments for prescription drugs on the quantity demanded and expenditure on prescription drugs, inpatient care and outpatient care. We allow for effects both in the year of the co-payment change and in the year following the change. Our results show that increases in prescription drug prices reduce both the use of and spending on prescription drugs. However, consumers substitute the use of outpatient care and inpatient care for prescription drug use, and the expenditure reductions on prescription drugs are largely offset by the increases in other spending.

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**Trade in Health Services: An Overview of the Current Debate**

In the mid 1970s the services sector replaced the industry sector as being the major contributor to GDP and employment in most OECD countries. Nonetheless its share in international trade is still small compared to goods trade even if it is faster growing. In 1995 with the conclusion of the General Agreement of Trade in Services (GATS), trade in services came also into focus of international trade consideration and strong liberalization efforts were made since then. This two aspects of globalisation and tertiarisation, nowadays increasingly concerns the Health Service sector as well. Typically being viewed as non-tradable Health Services become increasingly tradable, a mix of technological change and an institutional deregulation contribute to overcome this old paradigm. Even though the level of trade in this field is not yet very high, the challenges of modern health systems in developed and in developing countries – aging population, extended expectation of life, shortage of health professionals, sustainable founding of the health system, equal access regardless of income, region, ethnic or social affiliation etc. – may be solved partially with the help of increasing trade in Health Service. But can we assess the gains from trade in this field in the same way as in the classical trade debate of other goods and services. What are appropriate measures for welfare gains here? The presentation delivers an overview about the current debate and answers the following questions: What is the current level of trade in Health Services and how fast is it growing? What hinders trade and where is the scope for further liberalization? What are the potentials and the risks of the international exchange with Health Services?

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**Reform in Pharmaceutical Reimbursement in South Korea's National Health Insurance**

The most noticeable change in the Korean health care system was the establishment of the National Health Insurance (NHI) system. Successful development of the Korean NHI, however, was not without costs. With expansion of insurance coverage, demand and expectations of consumers have been continuously increasing. This dynamic aspect has been placing added financial pressure on the system. Facing financial deficits, as a good portion of rising NHI expenditure is attributable to extensive use of new medical technologies, the Korean health authority has been contemplating the use of economic data in reimbursement decisions of those newly introduced medical technologies, particularly pharmaceuticals.

Effective January 2007, South Korea's NHI implemented a reform in pharmaceutical reimbursement. By using economic data, the new policy aims to take cost-effectiveness and budget impact of newly introduced drugs into account in reimbursement decisions. When the policy will be fully implemented in 2008, South Korea will be the first Asian country officially to adopt the economic evaluation (EE) as a tool for resource allocation in health care.

This study looks at the background, objective, and expected outcome of the use of economic data in pharmaceutical reimbursement decisions in South Korea. It is hoped that a meaningful lesson could be offered to other countries who are also interested in using EE as a policy tool for health resource allocation.

## **Youngkong, Sitaporn**

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### **A Review of Economic Evaluation Studies in Thailand: Are the Data Good Enough to be Used in Decision Making and Whether They were Different Between Domestic and International Publications?**

Sitaporn Youngkong<sup>1</sup>, Yot Teerawattananon<sup>1</sup>, Usa Chaikledkaew<sup>2</sup>, Montarat Thavornchareonsap<sup>2</sup> and Suwanna Muger<sup>3</sup>

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**Introduction:** In many countries, including Thailand, there is increasing impetus to use economic evaluation to allow more explicit and transparent health care priority setting. However, an important question for policy makers in low- and middle-income countries is whether it is appropriate and feasible to introduce economic evaluation data into health care priority setting decisions. In addition to ethical, social and political challenges, information supply challenges need to be addressed.

**Objective:** The overall aim of this study was to analyse the quality, quantity and targeting of economic evaluation studies in Thailand and compare these characteristics between international and domestic literature.

**Methods:** This paper systematically reviews the international and national literature on economic evaluation of health technology in Thailand published between 1982 and 2005. For international literature, they included only journal articles available in PubMed, EMBASE (Ovid) and Academic Search Elite (EbscoH). Established databases from four major universities in Thailand namely Chulalongkorn University, Mahidol University, Khon Kaen University and Chiangmai University were searched to identify domestic literature, including journal articles, research reports, and master/PhD theses.

**Results:** The study identified 41 English articles published in international journals, 22 domestic journal articles, 5 research reports, and 23 master/PhD theses. It is noteworthy that there was no difference in terms of quality between articles published in international and domestic journals. Most of them did not report incremental cost-effectiveness ratios and perform uncertainty analysis. Furthermore, the number of publications has increased significantly in recent years with substantial improvement of quality of reporting and analysis. Nevertheless, the review shows an absence of economic evaluation publications in 15 of the top 20 major health problems in Thailand, indicating a poor distribution of research resources to determine costeffective interventions for diminishing disease burden within areas of major health problem.

**Conclusion:** If economic evaluation is only useful for policy makers when performed correctly and reported accurately, these findings depict information barriers to using economic evaluation to assist health decision-making processes in Thailand.

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## RESEARCH CONFERENCES

ESF-IfW Conference on the Global Health  
Economy

# The International Regulation of New Medical Technology: Health Technology Adoption in the European Union, North America, East Asia, and in the Developing World

Salzau Castle, Salzau (near Kiel) • Germany  
7-10 May 2007

Chair: **Finn Børlum Kristensen**, DACEHTA, Copenhagen &  
University of Southern Denmark, Odense, DK

Vice-Chair: **Lise Rochaix**, Haute Autorité de Santé (HAS), Paris &  
University of Aix Marseille, FR

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# Final Programme

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## Monday, 7 May

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- 16.00-19.00 Registration at the ESF desk and Hotel Check-In
- 19.00 Welcome Drink
- 19.30 Reception with Representatives from Schleswig-Holstein's State Government and the Initiativkreis Gesundheit
- Welcome Addresses by
- **Dennis J. Snower**, President of the Kiel Institute for the World Economy
  - **Hellmut Körner**, Secretary of State for Health Policy and Social Affairs in Schleswig-Holstein
  - **John Yfantopoulos**, Standing Committee for the Social Sciences at the European Science Foundation
- 20.00 Dinner

## Tuesday, 8 May

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- 08.45-09.00 Conference Opening

### Session 1: Theory and Policy Issues

Chair: **Finn Børlum Kristensen**, DACEHTA and University of Southern Denmark, DK

- 09.00-09.40 **M.N. Graham Dukes**  
University of Oslo, NO  
*Assessing the Empirical Evidence on the Costs and Benefits of Developing New Drugs – A Global Perspective*
- 09.40-10.20 **Finn Børlum Kristensen**  
DACEHTA and University of Southern Denmark, DK  
*The Role of Health Technology Assessments in Europe's Regulation of Health Technology – Present and Future*
- 10.20-11.00 **Christopher McCabe**  
Warwick Medical School, UK  
*Why Licensing Authorities Need to Consider the Net Value of New Drugs – Addressing the Tension between Licensing and Reimbursement*
- 11.00-11.30 Coffee Break
- 11.30-12.10 **Christina Sampogna**  
OECD, FR  
*Intellectual Property Rights and Other Policy Issues in the Development of Biotechnology – Are OECD Countries Converging?*
- 12.10-12.50 **Adrian Towse**  
Office of Health Economics, London, UK  
*Optimal Risk Sharing between Developers and Payers for New Medical Technologies*
- 13.00-14.15 Lunch

## Session 2: Health Technology Adoption and Regulation in the European Union

Chair: Lise Rochaix, University of Aix Marseille and Haute Autorité de Santé, FR

- 14.15-14.50 **Lieven Annemanns**  
University of Ghent, BE  
*How Early Should the Economic Evaluation of New Medical Technologies Begin?*
- 14.50-15.25 **Terkel Christiansen**  
University of Southern Denmark, DK  
*Diffusion of New Technologies for the Treatment of Aging-Related Diseases*
- 15.25-16.00 **Jørgen Dirach**  
Novo Nordisk, DK  
*The Innovative Medicines Initiative, a Public-Private Partnership to Benefit Patients and Society, Involving New Technologies and Processes for Medicines Development*
- 16.00-16.30 Coffee Break
- 16.30-17.05 **Guillem López-Casasnovas**  
University Pompeu-Fabra, ES  
*Comparative Efficiency of Reference Pricing for Drugs in Europe*
- 17.05-17.40 **Lise Rochaix**  
Haute Autorité de Santé and University of Aix Marseille, FR  
*Keeping Track of Rapidly Developing Technologies: The French Experience*
- 17.40-18.00 **Shenaz Ahmed** (short talk)  
University of Leeds, UK  
*Social and Ethnic Differences in Attitudes to Prenatal Testing and Termination of Pregnancy*
- 18.00-18.20 **Chiara de Waure** (short talk)  
Catholic University of the Sacred Heart, IT  
*Could Health Technology Assessment Be a Tool for Assessing New Vaccines? The Case of the Human Papilloma Virus*
- 18.20-18.40 **Lotte Steuten** (short talk)  
Health Economics Research Group, Brunel University, UK  
*Transferability of Economic Evaluations of Medical Devices – An Example of the Use of Fibrin Tissue Sealant in Orthopaedic Surgery*
- 18.40-19.00 **Imgard Vinck** (short talk)  
The Belgian Health Care Knowledge Centre, BE  
*Legal Aspects in the Assessment of New Medical Technologies in Belgium*
- 19.00-20.00 Dinner
- 20.15-21.45 Poster Session

**Wednesday, 9 May**

## Session 3: Health Technology Adoption and Regulation in North America, East Asia and Australia

**Chair: Michael Stolpe**, The Kiel Institute for the World Economy, DE

- 09.00-09.40      **Aaron S. Kesselheim**  
Harvard Medical School, US  
*Underuse of Generic Drugs in the United States: What is the Optimal Mix of Intellectual Property Rights and Adoption Incentives?*
- 09.40-10.20      **William B. Vogt**  
Carnegie Mellon University, US  
*Is Drug Coverage a Free Launch?*
- 10.20-11.00      **Jane Marceau**  
The University of New South Wales, AU  
*The Innovation Chain for Medical Technology in Australia*
- 11.00-11.30      Coffee Break
- 11.30-12.10      **Bong-Min Yang**  
Harvard and Seoul National University, KR  
*Pharmaceutical Pricing and Reimbursement in Korea*

## Session 4: Health Technology Adoption and Regulation in Low and Middle Income Countries

**Chair: Nick Drager**, World Health Organization, CH

- 12.10-12.50      **Steffen Groth**  
World Health Organization, CH  
*Access to Effective Medical Technology in Developing Countries – What Role for the United Nations?*
- 13.00-14.00      Lunch
- 14.15-14.50      **Patrick Leoni**  
National University of Ireland at Maynooth, IE  
*Designing the Financial Tools to Promote Universal Access to AIDS Care*
- 14.50-15.25      **Ajay Mahal**  
Harvard Department of Population and International Health, US  
*Diffusion of Medical Devices and Policy Implications in India*
- 15.25-16.00      **Adriana Velázquez**  
Centro Nacional de Excelencia Tecnológica en Salud, Ministry of Health, Mexico City, MX  
*Health Technology Adoption in Latin America – Institutions and Policies*
- 16.00-16.20      **Sima Marzban** (short talk)  
Iranian Health Technology Institute, IR  
*A Model for National Health Care Technology Selection and Use in Iran*
- 16.20-16.45      Coffee Break

16.45-17.20	<b>Peter Aaby</b> The State Serum Institute, Copenhagen, DK <i>Access to Vaccines in West Africa</i>
17.20-17.40	<b>Mintewab Bezabih</b> (short talk) Göteborg University, SE <i>Optimal Sequencing of Antiretroviral Treatment under Uncertainty and Irreversibility</i>
17.40-18.00	<b>Somesh Mathur</b> (short talk) Research and Information System for Developing Countries, IN <i>TRIPS – Issues, Impact and the Way Forward for Developing Countries, Including India</i>
18.00-18.20	<b>Inon Schenker</b> (short talk) The Jerusalem AIDS Project, IL <i>Cutting the Edge – Male Circumcision for HIV Prevention as an Example of Health Technology Transfer between Countries, Cultures and Contexts</i>
18.20-18.40	<b>Sitaporn Youngkong</b> (short talk) Ministry of Public Health, Bangkok, TH <i>A Systematic Review of the Economic Evaluation Literature in Thailand – Are the Data Good Enough to be Used by Policy Makers?</i>
18.40-19.40	Forward Look Plenary Discussion Chair: <b>Nick Drager</b> , World Health Organization, CH
20.15	Get-Together & Conference Dinner

### Thursday, 10 May

08.00-09.00	Hotel Check-Out
09.00-11.00	Conference Closing Session: Implications of Regulation for Medical Research Funding.
11.00	Lunch & Departure

### Abstracts, Posters & Short Oral Presentations

All invited speakers present their ideas and findings to the full plenum, with sufficient time for plenary discussions after each talk. All abstracts will be made available in a printed booklet of abstract that will also be downloadable from the Kiel Institute's conference website.

Outstanding junior scholars also give short oral presentations to the plenum. All abstracts not included in this programme are accepted as posters. Posters can be viewed during the breaks and in the dedicated poster session. The award for the best poster will be announced at the beginning of the forward look plenary session.