

Outline and objectives of the international research conference of the Kiel Institute for World Economics and the European Science Foundation on

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

to be held at Salzau Castle (near Kiel) in Germany, May 7 – 11, 2007

This conference is the second event in a series known as

*ESF–IfW Conferences on The Global Health Economy – A Partnership between the European
Science Foundation, the Kiel Institute for the World Economy, and Schleswig-Holstein’s
Biomedical „Inflammation at Interfaces“ Cluster of Excellence*

(i) Chairs

The 2007 conference in May will be chaired by Finn Børlum Kristensen (MD, PhD), and Lise Rochaix (MSc, PhD). Finn Børlum Kristensen is Professor at the University of Southern Denmark and Director of the Danish Centre for Health Technology Assessment (DACEHTA) at the National Board of Health. Lise Rochaix is Professor at the University of Aix Marseille, Member of the *Collège de la Haute Autorité de Santé*, and Chair de la *Commission Evaluation des Stratégies de Santé* (CE2S) at HAS.

(ii) Scientific scope

Rapid progress in medical technology is closely related to the process of globalization, i.e. the increasing integration of national markets for pharmaceuticals, medical devices, and other types of health-related technology. The globalization of these markets has created an historically unprecedented opportunity to better exploit the inherent economies of scale in the generation, evaluation and diffusion of new technology so that all countries may, in principle, obtain substantial gains in human welfare. A potential stumbling block, however, lies in the national regulation of access to new medical technology and in the wide variety of specific rules and procedures that national health systems use to protect their patients against adverse events, limit expenditure growth, improve the cost-effectiveness of health care delivery, and achieve other health-related policy objectives. National regulations may not only be suboptimal within their given country context, but may have – often unexpected -- additional repercussions through their interaction with international policies and supranational regulations.

The issues addressed in this conference thus lie at both the national and the international level, with a particular focus on the interaction between these two levels. At the national level, the

question is how the regulation of medical technology can be improved to serve a country's policy objectives. At the international level, the question is what sort of regulation will facilitate the further integration of national markets for medical technology. At present, national regulations are often inefficient on both counts, so that the incentives of decision makers in medical practice and in higher-level resource planning for health systems' development can be seriously constrained and distorted. This does not only slow down the adoption and diffusion of existing medical technology whose social benefits exceed costs, but also tends to reduce the private incentives to invest into new biomedical research worldwide. The evident lack of international coordination on many issues where at least some of it would be desirable needs to be recognized as an additional source of incentive problems.

Cooperation between medical scientists, health economists, and other social scientists, including legal scholars, will be essential to fully understand the multidimensional and sometimes conflicting nature of national health policy objectives, the suitability and validity of regulations to support the choices and trade-offs specific to each country, and the interactions between local and global regulations. All phases of technology adoption – from the introduction of new diagnostic methods into clinical decision making to the systematic assessment and economic evaluation of new technologies and the implementation of appropriate guidelines in therapeutic practice – will be considered. Examples of specific issues that may be addressed include the question of how best to take local epidemiological conditions and national health policy objectives into account when requirements for clinical trial information in national approval and reimbursement decisions are specified; the question of how new methods of genetic testing can be used effectively and in line with societal values; and the question of how regulations on the use of antibiotics can help stop the trend to increasing resistance mutations in bacteria.

(iii) Social relevance and timeliness

The social relevance of this conference has been highlighted by recent research findings, such as Becker et al. 2005; Nordhaus 2003), that attribute up to half of all welfare gains worldwide during the 20th century to the introduction and diffusion of new medical knowledge and technologies. We owe these findings to advances in economic methodology which allow for the first time to measure the aggregate economic value – at population level – of improvements in longevity and in the quality of life in a way that is consistent across time and across countries. At the same time, there is increasing evidence that national regulations restricting or delaying access to new technologies for the treatment of specific diseases could partly explain mortality differentials across countries. Differential access to new technologies may therefore contribute towards health inequalities, an issue that has recently become a top policy priority at the European level and elsewhere.

The timing of the conference is also in line with the increasing attention that is paid to these issues in world-wide trade negotiations, such as those about the agreement on trade-related intellectual property rights (TRIPs) that became part of the treaty for the World Trade Organization in 1994. The emergence of the HIV/AIDS pandemic and other threats to global

public health has moved the issue of access to medical technology in developing countries to the top of the global health policy agenda. Particular emphasis will therefore be placed on the diffusion of medical technology in the developing world where international organizations, such as the World Health Organization and the World Bank, have a pivotal role to play because relevant local expertise and experience is scarce and the institutions in charge of implementing effective regulation are often seriously understaffed.

Equally, issues of access and pricing regulations have become a source of growing tension among advanced countries. For instance, the US government has used diplomatic pressure on some countries like Australia to obtain a loosening of some of their regulatory controls on access and pricing in order to secure greater returns on innovation efforts by American medical technology companies. At the same time, many countries with a comprehensive value-based health care system have seen their ability to combine efficiency with equity in access undermined by a global market trend towards ever costlier medical technology, such as new patented chemical entities, often developed in US-based research laboratories. Many observers believe that the conflict between unconstrained global trajectories in medical technology and the specific priorities of national health systems will become even more serious as population ageing increases the per capita consumption of pharmaceuticals and utilization of other internationally traded medical technologies.

(iv) European dimension and added value

With regard to Europe's still fragmented markets for new medical technology, the conference will provide more than an important opportunity for cross-national learning about the effectiveness of specific regulatory systems and policies. Indeed, there is also an urgent need to explore the opportunities and constraints for more effective international cooperation in these matters. Moreover, there is a global dimension in further steps towards European integration in the regulation of medical technology. Europe now has a unique potential to expand the quantity and quality of its supply of new medical technology in a way that is consistent with the underlying values of Europe's national health systems. The European effort may hence become a beacon of light for the many countries that seek to base their health policies on similar values and are motivated by a similar preference for social cohesion – especially in developing Asia.

Our conference is expected to add value on three levels: the academic, the policy and the practical level. The findings presented at the conference and any subsequent research collaborations should also help to inform policy makers as to what steps to take at the European level to improve the diffusion of new technology and medical knowledge in clinical practice. An important task of the conference will hence be to take stock of existing institutions around the world and to involve industry experts, policy makers, administrators from various regulatory authorities and the users of medical technologies in the discussion of new developments in the theory and practice of medical technology regulation. In a similar vein, our conference also offers the opportunity to get selected practitioners from the health care industry involved in the discussion of future research collaborations. This should help to mobilize funding for such

projects and speed up the transfer of knowledge into the practice of health care. For this end, we also plan to host one-day tutorial workshops for fee-paying participants from the private and public health care sector in Germany and neighboring countries.

(v) Established meetings in this area of research

There are a variety of established meetings that are related to our conference theme, but none of these competes directly. For example, both the medical devices industry and the pharmaceutical industry have their own international meetings that address regulatory and policy issues, such as the 10th Global Harmonisation Task Force Conference for medical devices that was held in Lübeck in 2006 bringing together representatives from national medical device regulatory authorities and the regulated industry in Europe, Asia-Pacific, and North America. Likewise, there are numerous international meetings that address regulatory and policy issues in the global pharmaceutical industry. Many of these meetings are based in Europe and hosted by government agencies, including the European Commission, or industry associations. In addition, there are specialized professional societies and international networks of academics, managers and health care practitioners, such as the Association for Health Care Technology and Management (HCTM), Health Technology Assessment International (HTAi) and the International Network of Agencies for Health Technology Assessment (INAHTA), to only name a few, that organize regular meetings that may partially overlap with our agenda. International organizations with a special focus on health policy and regulatory issues, such as the OECD and the WHO, also host occasional conferences on related topics. But to our knowledge, there is no conference with a global outlook whose main purpose is to build an international and interdisciplinary academic research community on these issues.

Expected size: up to 120 participants (speakers included).

To participate in this agenda-setting conference, please use the application form on the conference website that is maintained by the European Science Foundation at www.esf.org/conferences

For inquiries about the strategy of the conference series, please contact Dr. Michael Stolpe, Coordinator of the Kiel Institute's Global Health Research Network, at michael.stolpe@ifw-kiel.de