OECD workshop on "Better Health through Bio-Medicine: Innovative Governance"

This workshop was held in Berlin, Germany on 27-28 September 2010.

Background

Agenda

Day 1 – 27 September 2010

Welcome Remarks : Purpose of the Workshop
Daniel BAHR, Member of Parliament, Parliamentary State Secretary of the German Federal Ministry of Health

Andrew WYCKOFF, Director, OECD Directorate for Science Technology and Industry

Mark BALE, Chairman of the OECD Task Force on Biomedicine and Health Innovation

Keynote Presentation: Alain POMPIDOU, President, French Academy of Technologies

Session 1: At the Root of the Governance Challenges

This session considered the main challenges to the governance of biomedical innovation. A few areas of biomedical innovation were used as examples for drawing out lessons learned.

Chair: Alain POMPIDOU, President, French Academy of Technologies

*Governance of stem cell therapy : Consequences on innovat*ion
Gustav STEINHOFF, The Reference and Translation Center for Cardiac Stem Cell Therapy, Rostock University, Germany

Nano-Medicine Policy : An overview of the main challenges
Travis M. EARLES, Office of Science and Technology Policy, United States

Bringing personalized medicine to healthcare : Lessons learned from Warfarin
Felix W. FRUEH, Vice President, R&D, Personalized Medicine, Medco Health Solutions, United States

Panel debate

- What are the governance challenges from these biomedical developments?
- Do our governance systems account for the opportunity risk of doing nothing? What governance models are emerging or are employed in OECD member countries to address these challenges?
- What are the goals of these new governance models?

- What governance models in these various fields, deliver more effective innovation (for example by establishing new organisational structures, streamlining regulatory review, more efficient communication etc)?

Keynote Presentation: *Affordable Whole Genome Sequencing: What will change?*

Robert COOK-DEEGAN, Center for Public Genomics, Center for Genome Ethics, Law & Policy, Institute for Genome Sciences & Policy, Duke University, Durham, North Carolina, United States

Round Table Debate

Whole genome-sequencing and genetic testing : The key challenges for governance
Discussant: Stuart HOGARTH, Department of Political Economy, King's College London, United Kingdom

Participants were asked to contribute their thoughts on the challenges resulting from whole genome screening and genetic testing. What are the range of issues that require urgent consideration as full-genome sequencing moves towards reality? How should health services be preparing for the onset of whole genome-sequencing as a clinical tool? What are the wider ethical, societal and regulatory issues related to the more extensive use and storage of personal genomic information. Does our health professional workforce have the necessary knowledge and skills to capitalise upon the benefits of next generation whole genome sequencing technologies?

Session 2: Streamlining Governance : Towards a more efficient clinical and translational research enterprise

Keynote Presentation: Promoting effective and coordinated policies and regulations for the conduct and oversight of clinical research

Margaret A. HAMBURG, Commissioner, United States Food and Drug Administration, United States

Chair: John LIM, Chief Executive Officer Health Sciences Authority, Singapore

Biomedical innovation involves a complex interplay of government, research institutions, professional organizations, private and public sector investigators, etc. The challenge is to unburden the flow of innovation from the bench to the bedside by addressing the key bottlenecks and by streamlining governance while maintaining effective safeguards. This session would review recent experience in the US, Singapore and the United Kingdom.

Integrating Clinical Research in Europe
Jacques DEMOTES-MAINARD, INSERM, Coordinator of the European Infrastructure Network, France

Globalization of biomedical clinical research: What are the main governance challenges? A private sector perspective
Detlef NIESE, Head Development External Affairs-Novartis, Switzerland

Panel debate

- What are the main instruments to streamline governance of biomedical innovation?
- What are the major challenges beyond the stratification of patient groups and the fact, that new therapeutic strategies do not necessarily confirm with the established licensing and review pathways?
- How do we create a more effective and efficient clinical research enterprise?
- How can governments ensure better policy coordination and coherence and the necessary feedback across the whole innovation cycle?
- What forms of organisational/institutional responses are necessary and emerging?

DAY 2 – 28 September 2010

Keynote Presentation

Managing Uncertainty : Financial and outcomes-based risk-sharing agreements
Sir Michael RAWLINS, Chairman of the National Institute of Health & Clinical Excellence (NICE), United Kingdom

Session 3: Managing Uncertainty

Chair: Eric ABADIE, Chairman of the Committee for Medicinal Products for Human Use (CHMP), France

The challenge for many policy makers is to create policies that can harness the benefits of technology and innovation, and at the same time achieve multiple health system objectives within the constraints of fiscal policy. Regulatory emphasis today is often inconsistent with the widely accepted notions that risk must be considered in the context of benefits, that understanding of the risks and benefits associated with a drug changes over a drug's life-cycle."

Balancing Market Access to New Drugs With the need for Benefit/Risk Data
Hans-Georg EICHLER, Senior Medical Officer EMA, United Kingdom

Canada's Progressive Licensing Framework
Cathy PARKER, Director of the Office of Policy and International, Collaboration, Health Canada Biologics and Genetic Therapies, Canada

Can we make approval and coverage decisions more predictable?
Thomas CUENI, Chairman EFPIAs Economic and Social Policy Committee

Panel debate

- How are governments combining the need to promote and sustain innovation with value to society?
- What models of risk-sharing are emerging?
- Are the emerging models limited to biomedical developments?
- How do current risk sharing agreements strengthen or complement other government policies aimed at increasing the efficiency of health innovation and at the same time, of health care systems?
- Do systems for sharing risk between the public/private sectors adequately match the uncertainties? If not what could be done?

Session 4: The Ever-Earlier Problem – International perspectives

Chair: Ingo HAERTEL, German Department of Health-Vice- Chair of the OECD Task Force on Biomedicine and Health Innovation

Policy makers are called into action to anticipate implications of biomedical research at "ever-earlier stages' of product/technology development. What new forms of cooperation and participatory regulatory models are emerging today to deal with the potential complexity of and the uncertainty and ambiguity of new biomedical technological developments?

The Implications of Synthetic Biology as an Open Source Research Model
François KÉPÈS, Director Programme Epigenomics, CNRS, Genopole, France

How can the Regulator and the Regulated Work Together?
Martha BRUMFIELD, Director of International Programs, Critical Path Institute, United States

Involving Stakeholders to move Regenerative Medicine from bench to bedside – German governance activities

Dagmar FRIESE, Head of Biotechnological Innovation, Ministry of Health, Germany

EC-Partnership models to facilitate cooperation with regulators
Arnd HOEVELER, Head of Unit, Research Directorate General, European Commission

Panel debate

- What participatory regulatory models are emerging today to deal with the potential complexity, uncertainty and ambiguity of new technological developments?
- What incentives are necessary to facilitate the informal process of sharing scientific and technical information between applicants and regulators?
- How can experience be widely shared, good and bad practice identified and dialogue furthered?
- How are these models changing the traditional roles of regulators as well as of the regulated?

Round Table Debate

Addressing societal issues
Engaging the public in an early debate
Stem cells, nano-medicine and direct-to consumers genetic testing

Discussants: Joyce TAIT, Innogen Centre, University of Edinburgh, Scotland
Bärbel HUESING, Fraunhofer Institute for Systems and Innovation Research, Germany

Participants were asked to contribute their thoughts on the challenges resulting from stem cell and direct to consumers genetic testing. What are the opportunities and challenges posed by, for example, stem cells, nano medicine and direct-to consumer genetic testing in engaging the public in an early and transparent public debate? How and at what stages do the various stakeholders need to be engaged? What can we learn from these different fields? Are there new issues arising with nano-medicine and synthetic biology?

Session 5: What next?

Chairs: OECD Secretariat

Round Table Debate

Main Policy Messages : Robert MAIN, Director Life Science Industries Branch-Industry Canada

This session brought together the OECD Secretariat, session chairs and country delegates and experts to discuss the policy issues and recommendations of the Workshop with a view to future developments.

The following key questions were considered:

- What governance model, deliver more effective innovation (for example by establishing new organisational structures, streamlining regulatory review, more efficient communication etc?
- How can regulators achieve "adaptive flexibility" in rule-making for a more efficient health innovation?
- What risk-sharing model, are emerging?
- What are the effects of increased engagement of stakeholders, including new forms of participatory regulation?
- How to achieve greater international convergence between regulatory regimes?
- How can the OECD Working Party on Biotechnology assist governments with these issues?

Closing Remarks