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DIRECTORATE FOR SCIENCE, TECHNOLOGY AND INDUSTRY
COMMITTEE FOR SCIENTIFIC AND TECHNOLOGICAL POLICY

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Working Party on Biotechnology

Synthesis Report of OECD work related to Biomedicine and Health Innovation

Annex 1 - Stocktake of OECD reports

19-21 November 2008

Delegates will find here attached the Annex to the Synthesis Report on Biomedicine and Health Innovation. It presents a stock take of recent OECD documents related to health innovation, summarises their content and identifies relevant policy messages that emerge from them.

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SECRETARIAT NOTE

This document is the Annex to the draft Synthesis Report on Biomedicine and Health Innovation [DSTI/STP/BIO(2008)24]. It presents a summary of recent documents from a variety of OECD sources that are related to health innovation.

ANNEX 1 –- SUMMARY OF OECD REPORTS ON BIOMEDICINE AND HEALTH INNOVATION

This Annex presents a stock take of the main messages that emerge from a number of recent OECD documents related to health innovation. The work done by the OECD has been categorized by the Task Force on Biomedicine and Health Innovation (TFBHI) into four different modules that are:

I. Access to Knowledge and Intellectual Property
II. New Business Models: The Creative Fusion and Exchange of Knowledge
III. The Governance of New Research and Health Infrastructures
IV. The Demand and Take-up of Health Innovations

For each module, this Annex presents the general policy issue addressed, a synopsis of each document that was deemed relevant to that policy issue, and the lessons and policy messages emerge from the documents with respect to the factors that influence the development, delivery and uptake biomedicine and other health innovations.

The documents are from varied sources within the OECD. Their committee provenance is indicated. Moreover, the documents are also sorted by level of country buy-in to the messages they contain. The classification is as follows and goes from high to low level of country consensus around the documents:

(1) *Instruments:* OECD Instruments are adopted by the OECD Council at a whole-of-government level. While Recommendations are not binding, they represent a commitment on the part of countries to implement the Recommendations. Guidelines or Ministerial Declarations adopted or issued by particular Committees also represent a willingness to implement but have not been vetted at a whole-of-government level.

(2) *Committee Reports:* Reports from Committees or Horizontal Projects have been discussed by committees and, depending on the Committee practice, are either declassified by them by consensus or are released under the authority of the Secretary General.

(3) *Workshops:* Workshop summaries or rapporteur's reports are simply a reporting on the outcomes of an OECD organised conference or workshop, they are usually discussed by Committees but may not represent a consensus view of Member countries.

(4) *Consultant Reports:* Consultancy reports are commissioned pieces of work which do not represent the views of the OECD. Committees may decide on their declassification, but the judgement is mostly about that of quality and accuracy of the work, rather than the political agreement with the content of the report. Similarly, the work from the Bioeconomy 2030 was done by a group of consultants outside a regular Committee.

MODULE 1 – ACCESS TO KNOWLEDGE AND INTELLECTUAL PROPERTY

1. Explanation of the policy issue

There is a tension between the need to protect intellectual property rights and the need to ensure their availability and accessibility for further innovation. OECD countries are interested in understanding the mix of mechanisms and practices that incentivise R&D (be it through proprietary rights or other benefits to the inventor) and that facilitate access to and use of the fruits of research for follow-on innovation and translation into new products and services. This set of documents discusses current intellectual property regimes and their impact on innovation and access. Also explored are emerging trends, mechanisms, and best practices for ensuring access and exploitation of intellectual assets so as to maximize innovative capacity in the economy.

Two main questions were explored by the TFBHI:

a. What are the "best practice" mechanisms/approaches for facilitating greater access to and value capture from knowledge and IP?

b. What policies and infrastructures are needed to facilitate the use of IP management practices that enhance the innovative capacity of the economy as a whole? For example, what policies and infrastructures improve the ability of actors to cooperate and to improve knowledge fusion and exchange?

2. Related work done in the OECD

Instruments

OECD, (2006). Principles *and Guidelines for Access to Research Data from Public Funding*. STI/TIP http://www.oecd.org/document/55/0,3343,en_2649_34293_38500791_1_1_1_37417,00.html

This set of principles and guidelines was composed in response to a Ministerial meeting in 2004 that expressed the need "to develop a set of OECD guidelines based on commonly agreed principles to facilitate optimal cost-effective access to digital research data from public funding". The Principles and Guidelines contained in this document should assist governments, research support and funding organisations, research institutions and researchers themselves in dealing with the barriers and challenges to the international sharing of, and access to, research data.

OECD, (2005). *Recommendation of the Council on the Licensing of Genetic Inventions.* [C(2005)149/REV1]. STI/BIO
http://www.oecd.org/document/26/0,3343,en_2649_34797_34317658_1_1_1_37417,00.html

These Guidelines offer principles and best practices for the licensing of genetic inventions used in human health care. They are targeted at all those involved in health R&D as well as those providing services in health, and particularly at those that involved in setting licensing norms and practices for

such inventions (e.g. funding bodies, technology transfer offices). The Guidelines are intended to assist both OECD and non-OECD governments in the development of governmental policies as well as in their efforts to encourage appropriate behaviour in the licensing and transferring of genetic inventions.

Reports for Committees

OECD, (2008). *"Knowledge Markets in the Life Sciences: Issues Paper."* [DSTI/STP/BIO(2008)8; see also DSTI/STP/BIO(2008)21 and DSTI/STP/BIO(2007)27/REV1] STI/BIO.

This is an issues paper prepared for an Expert Workshop on Knowledge Markets held in 2008. The workshop explored the factors that are influencing the creation of new 'markets' for knowledge-based assets, including intellectual property, information, data, goods and services; as well as identify what strategies different developers and users of knowledge are using to better identify, access, exploit, and create value from intellectual assets.

OECD, (2008). "*Globalisation and Open Innovation – Highlights and full Report"*. [DSTI/STP/TIP(2007)10], STI/TIP.

This is a summary report of a conference hosted by the OECD and the Dutch Ministry of Economic Affairs on "Globalisation and Open Innovation" about the policy implications of the acceleration in the globalisation of research and innovation and the shift towards "open innovation" strategies in companies. The discussion centred around three main topics: *i)* the rise of open innovation and open business models in the context of globalisation; *ii)* the evidence for open innovation, drawing mainly on company case studies; and *iii)* the implications for science, technology and innovation policies.

OECD, (2008). "*Intellectual Assets and Value Creation: Synthesis Report"*. STP/CIIE

This synthesis report follows- up on the *Creating Value from Intellectual Assets* report of 2006. It was endorsed by Ministers. In order to deepen understanding of intellectual assets in relation to innovation and value creation, they are looked at on three levels: Macro-level (national accounts and estimations of investment in intellectual assets), regional-level (the regional dimension of innovation, firm location and linkage) and firm level (corporate reporting, value creation, SMEs).

OECD, (2007). *"Collaborative Mechanisms for the Management of Intellectual Property."* [DSTI/STP/BIO(2007)8/REV1] DSTI/BIO.

This report provides the context for the use of collaborative mechanisms, for the management of intellectual property exploring different types of collaborative mechanisms, as well as their nature, scope, structure and application. It also examines the possible employment of these mechanisms for stimulating innovation, encouraging access for R&D and for the diffusion of technology.

OECD (2007). "*The Economic Impact of Counterfeiting and Piracy of Pharmaceuticals"*. [DSTI/STP/IND(2007)9/PART4/REV1] DSTI/IND. www.oecd.org/dataoecd/11/38/38704571.pdf

This report is the result of a horizontal OECD project on the "Economic Impact of Counterfeiting and Piracy." It assesses the structure and scope of the market for counterfeit and pirated products and presents frameworks both for assessing the economic effects of such products and the effectiveness of policies and other initiatives to combat counterfeiting. Several industries are examined in detail, among which the pharmaceutical industry. Finally, suggestions are made for strengthening policies and practices that combat counterfeiting and piracy.

OECD, (2006). *"Research Exemptions."* [DSTI/STP/TIP(2006)15; see also DSTI/DOC(2006)2].

Two documents related to research exemptions: One is a summary report of the Madrid Conference on Research Use of Patented Inventions held in 2006, while the second is a review of the issues related to research access to patented inventions. The key question addressed is how to ensure access to inventions for follow-on research, while simultaneously providing incentives for the original inventor. While several options for research exemptions are examined, the authors conclude that more research is needed to ascertain whether the absence of research exemptions is in fact having a deleterious effect on scientific inquiry.

OECD (2006). "Valuation and Exploitation of Intellectual Property." CSTP.
http://www.oecd.org/dataoecd/62/52/37031481.pdf

This STI Working Paper addresses the valuation and exploitation of intellectual property, not just by developing products based on one's own patents but also by licensing them to other firms or public research organisations (PROs), using them as bargaining chips in negotiations with other firms, and as a means of attracting external financing from institutional investors, banks, venture capitalists and other sources.

OECD, (2004). *"Intellectual Property Rights and Competition Policy with a Focus on Biotechnology,"* Roundtable materials and background note. DAF/COMP. www.oecd.org/dataoecd/61/48/34306055.pdf

This document presents the papers for a Roundtable discussion on Intellectual Property Rights held by the Competition Committee in June 2004 (a Background Note, Executive Summary, individual country contributions). The papers consider the interdependence of competition and intellectual property policy, and the role of competition and IP agencies in assuring that IP does not impede fair competition.

OECD, (2003). "*Genetic Inventions, Intellectual Property Rights, and Licensing Practices: Evidence and Policies"*. DSTI/BIO. http://www.oecd.org/dataoecd/42/21/2491084.pdf

This publication is based on a 2002 expert workshop which discussed the challenges raised by the proliferation of patents on genetic material (e.g. blocking patents, patent thickets, freedom to operate), and the licensing practices of public and private actors. It discusses the advantages and disadvantages of various policy measures which could be used to address access issues for genetic inventions.

Workshop summaries

OECD (2007). "Report of the High Level Forum on the Availability of Medicines for Neglected and Emerging Infectious Diseases." DSTI/BIO and DCD/PCD. [DSTI/STP/BIO(2007)23/REV1, see also DSTI/STP/BIO(2007)6]
http://www.oecd.org/document/45/0,3343,en_2649_34537_39163757_1_1_1_1,00.html

This document reviews the outcomes of the OECD High-Level Forum on Medicines for Neglected and Emerging Infectious Diseases: Policy Coherence to Enhance the Availability which was held in the Netherlands in 2007. The High Level Forum issued the Noordwijk Medicines Agenda, (NMA) which summarises the main actions participants at the Forum agreed were necessary to accelerate the development and delivery of new medicines, vaccines and diagnostics for the emerging and neglected infectious diseases that primarily affect developing countries.

Consultant Reports

Gold, R., M. Herder, M. Trommetter, (2008). "The Role of Biotechnology Intellectual Property Rights in the Bioeconomy of 2030," *BioEconomy 2030.* (Forthcoming) SGE/IFP.
http://www.oecd.org/dataoecd/11/58/40925999.pdf

This paper predicts the role that intellectual property will play in the Bioeconomy of 2030. It argues that while it will remain important, IP will not shape the Bioeconomy. If countries, industry and public institutions manage to develop collaborative platforms for sharing and disseminating knowledge and innovation, then we can expect a dynamic Bioeconomy with reduced regulatory costs in 2030. If such platforms are not created, we can expect increased transaction costs, increased regulatory costs and less innovation.

Herder, M. and Gold, R. (2008). "Intellectual Property Issues in Biotechnology: Health and Industry," *Bioeconomy 2030.* (Forthcoming). SGE/IFP. www.oecd.org/dataoecd/16/9/40181372.pdf

This paper tackles the question of whether the current IP system incentivises innovation or impedes it, and how this affects health and industrial outcomes. The conclusion is that we still lack knowledge and appropriate indicators to assess how IP rights are driving or impeding innovation.

Chris Dent, Paul Jensen, Sophie Waller and Beth Webster, (2006). "*Research Use of Patented Knowledge: A Review".* DSTI/DOC(2006)2, DSTI/TIP. www.oecd.org/dataoecd/15/16/36311146.pdf

This Working Paper reviews issues related to research access to patented inventions, with a particular focus on the role of research exemptions (or experimental use exemptions) in protecting such access. It outlines factors that may affect the ability of researchers to access patented inventions for legitimate research purposes, it reviews evidence of current and anticipated limitations on access, and explores different options for the formulation of research exemptions that balance research use and patent holder's rights.

3. Main messages extracted from the publications above

1. What are the norms of IP protection and management discussed and how do the different mechanisms or practices affect competition, collaboration, the transfer and access to knowledge, and knowledge translation?	
Intellectual Property Issues in Biotechnology: Health and Industry	Patents can create two types of access problems: firstly "blocking" or "hold-up" where patent-holders refuse to license necessary inventions to researchers or health care providers or require license fees that are prohibitively expensive for the would-be user. Secondly, "royalty stacking" or the "tragedy of the anticommons", where the sum of costs of securing all the necessary licenses is prohibitive or has transaction costs that are too high. The authors also pay particular attention to the development divide arguing that the western IPS system creates insufficient incentives to address the particular health and industrial needs of the developing world. They don't deliver products that are much needed in such countries, nor do they optimize existing products for delivery and use in these countries
Genetic Inventions, Intellectual Property Rights, and Licensing Practices	The proliferation of patents on genetic inventions has changed the IP landscape in the life sciences, and there are fears this may have had adverse effects on access to knowledge and thus the potential for innovation. At the same time, the licensing system is adapting rapidly to the complex IP landscape and self regulating mechanisms are evolving in parallel to the formal laws. These include patent pools, clearinghouses, and collective licensing, aimed at maintaining access. • While the workshop evidenced that patents on genetic inventions are supported by the majority of experts, a number of concerns were also noted: • Rise in patents on genes causes patent thickets and royalty stacking concerns. But research shows that the number of patents that actually create obstacles to public use or market entry seems quite small. • Participants were particularly concerned about cases where patents on genes may prevent access for research, for example for developing genetic tests. The cost associated with licensing may be prohibitively high, potentially preventing such diagnostic tests from being developed. • The rise of patents with reach through claims also cause concern about access for research purposes. • Research exemptions are often not well defined (although it is acknowledged that this may be positive in that is allows flexibility).
Intellectual Property Rights and Competition Policy with a Focus on Biotechnology Roundtable materials and background note	Several IP-related practices are examined from the perspective of a competition agencies: • Vertical and horizontal licensing agreements: horizontal licensing agreements are more likely to cause competition concerns than vertical licensing. • A grant-back obligation is a provision in a licensing arrangement that requires the licensee to grant a license on any improvements it patents related to the original invention back to the licensor. Grant-back obligations on severable improvements (those that can be used by licensees without infringing the original invention) may damage incentives for follow on innovation and only prologue the licensors market power. On the other hand grant-backs are a way to finance a cash-poor licensee by sharing the fruits of their research with licensors, but should preferably only be used sparingly.

	• Patent pools: These generally make it easier to exploit technology and foster innovation. However, they can be anti-competitive when the pool includes substitute patents thereby jointly selling something that would usually be competing technologies. Also, patents that are non-essential (ie patents that have substitutes outside the pool) may foreclose third parties and eliminate competition. (like bundling software) • Unilateral refusal to license & mandatory licensing: There is disagreement about whether the refusal to license is anti-competitive and if compulsory licensing should be used as a remedy. Compulsory licensing can have disadvantages and may burden innovation and competition.
Counterfeiting and Piracy of Pharmaceuticals and Executive Summary	In addition to the health risks consumers are exposed to from counterfeited pharmaceutical products, these products may also have an adverse effect on the value of IP of legitimate products. However, to date, there are no available statistics that counterfeiting activities are directly impacting the value of IPRs in the pharmaceutical sector. The effects of the counterfeit pharmaceutical market on innovation are not explicitly discussed in this report.
Research Exemptions	Various options for research exemptions are being explored - research exemptions can be written into the law (statutory) or adopted in jurisprudence (common law). Statutory research exemptions provide clarity and security whereas common law defences provide greater flexibility but less certainty, as the interpretation of the law may change over time subject to court decisions. Parallel to these, some alternative practices are developing. Each of these has certain advantages and disadvantages. • Research exemptions model based on copyright law exemptions • Patent portfolios are increasingly used to ensure freedom to operate and co-operate in research • Informal co-operative communities (*e.g.* open-licensing schemes, patent pools for defensive purposes) One problem is that international differences in research exemptions and patent systems mean that organizations performing global R&D might not benefit from exemptions as they could face litigation risks in certain countries.
Collaborative Mechanisms for the Management of Intellectual Property	The various practices and mechanisms that are explored are: • Patent pools • Patent clearinghouses: matchmaking between potential licensor and licensee • Consortia/public-private partnerships • Open Innovation (and it is noted that there is still confusion about the definition of this term) • Advance Market Commitments: subsidizing future purchase of a product still being developed. • Prizes: Monetary awards for the solution to a clearly defined research problem. This is particularly used for research on emerging and neglected infectious diseases. • Patent Buy-Outs: where an entity (ie government or charitable organisation) purchases the patent rights to a product meeting specific conditions/objectives, to then place it in the public domain.

	The idea behind most mechanisms is to allow for different research entities to collaborate at various stages of the innovation cycle. Consortia, for example, mostly share pre-competitive data for the sake of research. Patent clearinghouses on the other can facilitate the establishment of a license by matching potential collaborators. Prizes may expand the network of potential collaborators or contributors to a given research question. Some forms of collaborative mechanisms may, *prima facie*, present anti-competitive characteristics. However, it now appears that a number of competition authorities are becoming more open to the use of collaborative mechanisms, in light of their potential for encouraging pro-competitive behaviour, such as increasing access to goods, technologies, information and services. The various mechanisms all intend to facilitate access to knowledge but achieve this in different ways. Patent pools for example remove patent thickets that might hinder access; clearinghouses remove transaction costs in finding the sought after license for a patent and technology; prizes make a research question more widely available and thereby create access to previously untapped pools.
Knowledge Markets	Knowledge Markets are mechanisms where knowledge can be shared, pooled and traded, facilitating the access to and exploitation of existing knowledge assets. They include mechanisms like consortia, patent pools, clearinghouses, collaborative knowledge networks, IP auctions, matching or brokering services, etc. These are increasingly being applied to the life sciences, creating new norms and practices for intellectual asset access and exploitation. New markets for knowledge assets to be exploited also create new forms of competition and new business models. For example the acquisition of knowledge through prizes (eg InnoCentive) creates competition between potential suppliers of knowledge.
Globalisation and Open Innovation – Highlights and full Report	Different speakers had different characterisations of the term 'open innovation' and the implications of this trend on business models and IPR. One speaker (Pieter Adriaans) for example categorised different models as follows: • Purchasing based: spin-offs, research projects, etc • Collaborative innovation: PPPs, Alliances, where partnerships and mutual long term expectations are built between research entities • Open access innovation: where users can innovate, many hands, light work, in an open network Another speaker (Henry Chesbrough) pointed out several important implications of the emergence of open innovation on the management of intellectual property rights: • While traditionally IP captures value by giving owners an advantage over competitors through technological and market exclusion, in an open business model it can be used strategically to create value outside core business areas (e.g. through licensing to other firms) or through standards-setting. • Furthermore, by offering access to IP via a common area or "intellectual commons" users and suppliers can create new value. When two parties have conflicting claims to areas covered by intellectual property, there may also be an opportunity for collaboration. • Another implication for IPRs from the open innovation model is the development of a market for intellectual property. As IP becomes more important to value creation, it is becoming more tradable. This is illustrated by the beginnings of a secondary market for IP that can be used to collaterise corporate debt. This idea is being expanded in the Knowledge Markets project.

OECD Principles and Guidelines for Access to Research Data from Public Funding	Adopting the guidelines will help promote a culture of openness and sharing research data among public research communities. The Guidelines are aimed at stimulating the exchange of knowledge and best-practices, and leading to open access and better exploitation of scientific data derived from publicly funded research.
Valuation and Exploitation of Intellectual Property	The two important steps of IP management that are explored in this paper are exploitation and valuation of intellectual property. • Efficient technology markets can improve innovation processes by facilitating exchanges of patented inventions (via sale or licensing) among private and public sector actors that can put inventions in the hands of those most able to commercialise them. Improved valuation can facilitate not only technology transfer, but a full range of channels for exploiting IP such as decision to file a patent and investment in firms which hold patents.
Report of the High Level Forum on the Availability of Medicines for Neglected and Emerging Infectious Diseases	The NMA states that: • The protection and use of intellectual property rights (IPRs) are important in encouraging investments in research and development of medicines, vaccines, and diagnostics but are not sufficient to stimulate innovation for neglected and emerging infectious diseases. Complementary reward systems may also play an important role. • New approaches to more open innovation and collaborative research, as well as access to knowledge, can further increase the efficiency and lower the costs of developing new, safe and effective medicines, vaccines and diagnostics for neglected and emerging infectious diseases as well as broaden the involvement of researchers, academic institutions, laboratories and companies globally. • There is a need to explore and evaluate the value of sustainable collaborative mechanisms for access to IPRs (such as patent pools or other IP and data management entities). Additionally, there is a need to better understand how alternative policy mechanisms to reward innovation (*e.g.* advanced market commitments, prize fund models, valorisation of intellectual assets) could contribute to the development of medicines, and what mix of mechanisms may be desirable.

2. What are the "best practice" mechanisms/approaches for facilitating greater access to- and value capture from knowledge and IP?	
Intellectual Property Rights and Competition Policy with a Focus on Biotechnology Roundtable materials and background note	In licensing agreements, competition agencies should distinguish between horizontal and vertical agreements. Patent pools should only include complementary and essential technologies. Grant-back obligations should be on non-severable improvements but not on severable improvements.
Research Exemptions	High-quality patents should be characterised by a sufficient level of inventiveness and an appropriate level of protection relative to their contribution to the state of the art (*e.g.* claims granted only for disclosed specific uses). Any research exemption should have the following characteristics: • Provide greater clarity for researchers • Avoid being too rigid in interpretation • Not impede scientific development or investment in research • No reflect a substantial shift in the understanding of patent law • Contribute to international harmonisation of patent law
Collaborative Mechanisms for the Management of Intellectual Property	All mechanisms described in this paper are 'desirable' when the contextual factors are such that they can successfully be established and run. What these factors are and what allows for a certain mechanism to work or not, still requires further consideration.
Guidelines for the Licensing of Genetic Inventions	The entire document is a set of best practices relevant for the licensing of IP on genetic inventions. On a very general level, licensing practices should fulfil the following criterion: • Licensing practices should foster innovation in the development of new genetic inventions related to human health care and should ensure that therapeutics, diagnostics and other products and services employing genetic inventions are made readily available on a reasonable basis. • Licensing practices should encourage the rapid dissemination of information concerning genetic inventions. • Licensing practices should provide an opportunity for licensors and licensees to obtain returns from their investment with respect to genetic inventions. Licensees and licensors should have reasonable certainty over their rights and the limitations to those rights in relation to genetic inventions.
Valuation and Exploitation of Intellectual Property	This paper explores practices that are conductive to the valuation and exploitation of intellectual assets. Crucial is that patents granted should be of high quality, the criteria thereof being that they are enforceable in the market place, can withstand judicial challenges, and are issued in a timely fashion. An example practice that incentivises licensing (exploitation) of IP is that the patent offices of Germany, France and the United Kingdom have introduced a system of licences-of-right that offer patent holders a discount on renewal fees (of around 40% to 50%) in exchange for their agreement to offer non-exclusive licences to any party that requests one.

Intellectual Assets and Value Creation: Synthesis Report	When well managed, the average return on investment in intellectual assets can be large. In order to maximize return, leading firms have increased the efficiency of their R&D processes by linking internal R&D activities more closely to their business strategy, while relying on external sources to gain access to complementary knowledge and round out technology portfolios.

3. *What infrastructures and policies are needed to facilitate the use of IP management practices that enhance the innovative capacity of the economy as a whole. For example, what policies and infrastructures improve the ability of actors to cooperate and to improve knowledge fusion and exchange?*	
The Role of Biotechnology Intellectual Property Rights in the Bioeconomy of 2030	To obtain the full benefits of health biotechnology in 2030, greater collaboration will be needed on at least two fronts. First, greater collaboration between industry partners and the public sector will be required to help identify new drug targets. Second, to better enable regulators to evaluate the safety and efficacy of new medication, industry will need to share platforms with regulators across the world. Both sets of collaborations will depend on developing strategies that open access to proprietary technologies and to share the benefits arising from their use.
Genetic Inventions, Intellectual Property Rights, and Licensing Practices	Policies should target the access problems without distorting incentives to innovate. Could be legislative, administrative or regulatory, latter two are generally preferred. Possible policy interventions are 'raising the bar' for granting patents of genetic inventions, the use of compulsory licensing, or expanding research exemptions. Further impact studies are necessary before any of these are to be taken forward. Self-regulation practices should be encouraged by government. Defining the parameters of research exemptions is difficult and it may perhaps more effective to keep present uncertainty to avoid more confusion.
Intellectual Property Rights and Competition Policy with a Focus on Biotechnology Roundtable materials and background note	What is the role of competition and IP agencies in ensuring fair competition in the IP dynamics? • Given the young, dynamic, and complex biotech industry where a lot of weight is put on IP, IP agencies should when possible have personnel trained in biotech and IP in order to ensure that only inventions deserving protection are granted patents. • Competition agencies should not become involved in the IP granting process itself but can undertake a number of measures to promote greater consideration of competition issues by IP agencies. • Competition agencies should consider publishing a set of guidelines about how they analyse licensing and other agreements involving IP.
Research Exemptions	Beyond putting in place the formal research exemptions, government has a role to play in facilitating access to protected data for the sake of research. Examples are: • Competition policy can be used to guarantee affordable and widespread licensing of foundational inventions and essential research tools protected by patents by monitoring the behaviour of licensors. • Governments often retain the right to inventions developed with government funding or can require compulsory licensing in certain situations.

Collaborative Mechanisms for the Management of Intellectual Property	Some of the mechanisms require direct government funding (such as PPPs, AMCs and Patent Buy-outs) whereas others may need the oversight of government and possibly patent attorneys to ensure their compliance with regulation (*e.g.* the establishment of a patent pool). The creation of these mechanisms should be facilitated. More research is needed to determine what environment allows for a certain collaborative mechanisms to take place in a certain context.
Globalisation and Open Innovation – Highlights and full Report	Policies that protect domestic industries or limit foreign competition are inconsistent with open innovation. Government should focus more on SMEs and universities rather than incumbent firms. In universities, excellence should be promoted and incentives provided for researchers to collaborate with industry. Also, participants called for changes in the way universities and public research organisations are evaluated and the way research is rewarded so as to promote greater impact (quality) rather than production (quantity). User-driven innovation should be facilitated by supporting the ability of users to modify what they buy, and providing infrastructure for distributed innovation. Balancing IPR and knowledge sharing: some IP policies might be counterproductive to open innovation. Government might have a role in supporting the capacity for knowledge sharing, (*e.g.* through open source platforms and intellectual commons)
OECD Principles and Guidelines for Access to Research Data from Public Funding	This is a policy tool as such. See whole document for guidelines to ensuring access and sharing of data derived of publicly funded research.
Valuation and exploitation of Intellectual Property	Governments have a number of mechanisms at their disposal to encourage the valuation and exploitation of intellectual property. • Patent and license information should be disclosed and searchable to parties that might be interested in licensing agreements. Initiatives such as CORDIS and BMBF (Germany) exist already to do this, using ICT to facilitate the disclosure of information • Match making services between buyers and sellers of technology should be facilitated. Example activities are patent licensing fairs and patent licensing advisors • Legislation should support the ability of public research organisations to patent and license. The Bayh-Dole act does this in US and other countries have similar initiatives. • Effective technology licensing offices need staff that have broad business experience as well as technological depth. HR should be formed and supplied accordingly. • Training programs to enhance awareness of IP issues have been instated in a number of member countries and are seen as good practice, as is outreach to give support to SME in the patenting process (either financially or through training etc) • The development and usage of tools that allow patents to be valued should be encouraged. For example IPscore developed by the Danish Patent office. Valuation services are useful to patent holders who wish to take out bank loans and use patents as collateral. • Reporting guidelines are being developed and should be harmonized. Guidelines should assist firms in preparing reports with quantitative and qualitative data about their intellectual assets.
Intellectual Assets and Value Creation: Synthesis Report	Case studies show that reporting Intellectual Assets (IA) leads to better relation with creditor and opens up new sources of financial capital, because the IA can be used as collateral.
Report of the High	Demand for essential medical technologies should be forecasted.

Level Forum on the Availability of Medicines for Neglected and Emerging Infectious	Create information clearinghouses of ongoing R&D to reduce the duplication of efforts. Facilitate the development and operation of a sustainable architecture for the sharing and exchange of knowledge, data and research tools necessary for the discovery of medicines, vaccines and diagnostics for neglected and emerging infectious diseases. Create a framework to facilitate voluntary contributions of advice, skills, and infrastructure access from industry and the public sector. Encourage developing countries to participate in PDPs focusing on diseases endemic in their countries. This should be coupled with capacity building.

4. *What infrastructures and policies are needed to facilitate the use of IP management practices that enhance the innovative capacity of the economy as a whole? For example, what policies and infrastructures improve the ability of actors to cooperate and to improve knowledge fusion and exchange?*	
The Role of Biotechnology Intellectual Property Rights in the Bioeconomy of 2030	To obtain the full benefits of health biotechnology in 2030, greater collaboration will be needed on at least two fronts. First, greater collaboration between industry partners and the public sector will be required to help identify new drug targets. Second, to better enable regulators to evaluate the safety and efficacy of new medication, industry will need to share platforms with regulators across the world. Both sets of collaborations will depend on developing strategies that open access to proprietary technologies and to share the benefits arising from their use.
Genetic Inventions, Intellectual Property Rights, and Licensing Practices	Policies should target the access problems without distorting incentives to innovate. Could be legislative, administrative or regulatory, latter two are generally preferred. Possible policy interventions are 'raising the bar' for granting patents of genetic inventions, the use of compulsory licensing, or expanding research exemptions. Further impact studies are necessary before any of these are to be taken forward. Self-regulation practices should be encouraged by government. Defining the parameters of research exemptions is difficult and it may perhaps more effective to keep present uncertainty to avoid more confusion.
Intellectual Property Rights and Competition Policy with a Focus on Biotechnology Roundtable materials and background note	What is the role of competition and IP agencies in ensuring fair competition in the IP dynamics? • Given the young, dynamic, and complex biotech industry where a lot of weight is put on IP, IP agencies should when possible have personnel trained in biotech and IP in order to ensure that only inventions deserving protection are granted patents. • Competition agencies should not become involved in the IP granting process itself but can undertake a number of measures to promote greater consideration of competition issues by IP agencies. • Competition agencies should consider publishing a set of guidelines about how they analyse licensing and other agreements involving IP.
Research Exemptions	Beyond putting in place the formal research exemptions, government has a role to play in facilitating access to protected data for the sake of research. Examples are: • Competition policy can be used to guarantee affordable and widespread licensing of foundational inventions and essential research tools protected by patents by monitoring the behaviour of licensors. • Governments often retain the right to inventions developed with government funding or can require compulsory licensing in certain situations.

Collaborative Mechanisms for the Management of Intellectual Property	Some of the mechanisms require direct government funding (such as PPPs, AMCs and Patent Buy-outs) whereas others may need the oversight of government and possibly patent attorneys to ensure their compliance with regulation (*e.g.* the establishment of a patent pool). The creation of these mechanisms should be facilitated. More research is needed to determine what environment allows for a certain collaborative mechanisms to take place in a certain context.
Globalisation and Open Innovation – Highlights and full Report	Policies that protect domestic industries or limit foreign competition are inconsistent with open innovation. Government should focus more on SMEs and universities rather than incumbent firms. In universities, excellence should be promoted and incentives provided for researchers to collaborate with industry. Also, participants called for changes in the way universities and public research organisations are evaluated and the way research is rewarded so as to promote greater impact (quality) rather than production (quantity). User-driven innovation should be facilitated by supporting the ability of users to modify what they buy, and providing infrastructure for distributed innovation. Balancing IPR and knowledge sharing: some IP policies might be counterproductive to open innovation. Government might have a role in supporting the capacity for knowledge sharing, (*e.g.* through open source platforms and intellectual commons)
OECD Principles and Guidelines for Access to Research Data from Public Funding	This is a policy tool as such. See whole document for guidelines to ensuring access and sharing of data derived of publicly funded research.
Valuation and exploitation of Intellectual Property	Governments have a number of mechanisms at their disposal to encourage the valuation and exploitation of intellectual property. • Patent and license information should be disclosed and searchable to parties that might be interested in licensing agreements. Initiatives such as CORDIS and BMBF (Germany) exist already to do this, using ICT to facilitate the disclosure of information • Match making services between buyers and sellers of technology should be facilitated. Example activities are patent licensing fairs and patent licensing advisors • Legislation should support the ability of public research organisations to patent and license. The Bayh-Dole act does this in US and other countries have similar initiatives. • Effective technology licensing offices need staff that have broad business experience as well as technological depth. HR should be formed and supplied accordingly. • Training programs to enhance awareness of IP issues have been instated in a number of member countries and are seen as good practice, as is outreach to give support to SME in the patenting process (either financially or through training etc) • The development and usage of tools that allow patents to be valued should be encouraged. For example IPscore developed by the Danish Patent office. Valuation services are useful to patent holders who wish to take out bank loans and use patents as collateral. • Reporting guidelines are being developed and should be harmonized. Guidelines should assist firms in preparing reports with quantitative and qualitative data about their intellectual assets.
Intellectual Assets and Value Creation:	Case studies show that reporting Intellectual Assets (IA) leads to better relation with creditor and opens up new sources of financial capital, because the IA can be used as collateral.

Synthesis Report	
Report of the High Level Forum on the Availability of Medicines for Neglected and Emerging Infectious Diseases	• Demand for essential medical technologies should be forecasted. • Create information clearinghouses of ongoing R&D to reduce the duplication of efforts. • Facilitate the development and operation of a sustainable architecture for the sharing and exchange of knowledge, data and research tools necessary for the discovery of medicines, vaccines and diagnostics for neglected and emerging infectious diseases. • Create a framework to facilitate voluntary contributions of advice, skills, and infrastructure access from industry and the public sector. • Encourage developing countries to participate in PDPs focusing on diseases endemic in their countries. This should be coupled with capacity building

II. MODULE 2 – NEW BUSINESS MODELS: THE CREATIVE FUSION AND EXCHANGE OF KNOWLEDGE

1. Explanation of the policy issue

The private sector has the central role in the process of developing and delivering new health products and services. Business strategies, knowledge sourcing and management, interfirm relationships in the health sector have been the subject of many OECD documents. As a short hand, the OECD refers to these topics as research and business models.

This module focuses on the processes of knowledge creation, diffusion and exploitation in the health sector. Some of the documents explore the health research system architecture: who are the different actors and enterprises involved in innovation and what are the channels they employ for accessing and commercialising knowledge and innovations (e.g. academic or government research, inter-business or public-private partnerships, internal investment in R&D, non technological and user-driven innovation). Some of the documents explore how and why inter-firm and inter-organisation relationships are changing. New types of partnerships, new business models, the integration of different technologies and sectors, new way of thinking, are driving a new vision of how to apply science and technology for innovations in health. Some of the documents focus on the impact of new biomedical technologies on business models (and vice versa).

2. Related work done in the OECD

Committee Reports

OECD, (2008). *"Knowledge Markets in the Life Sciences: Issues Paper."* [DSTI/STP/BIO(2008)8; see also DSTI/STP/BIO(2008)21 and DSTI/STP/BIO(2007)27/REV1] STI/BIO.

> This is an issues paper prepared for an Expert Workshop on Knowledge Markets held in 2008. The workshop explored the factors that are influencing the creation of new 'markets' for knowledge-based assets, including intellectual property, information, data, goods and services; as well as identify what strategies different developers and users of knowledge are using to better identify, access, exploit, and create value from intellectual assets.

OECD, (2008). "*Globalisation and Open Innovation – Highlights and full Report"*. [DSTI/STP/TIP(2007)10], STI/TIP.

> This is a summary report of a conference hosted by the OECD and the Dutch Ministry of Economic Affairs on "Globalisation and Open Innovation" about the policy implications of the acceleration in the globalisation of research and innovation and the shift towards "open innovation" strategies in companies. The discussion centred around three main topics: *i)* the rise of open innovation and open business models in the context of globalisation; *ii)* the evidence for open innovation, drawing mainly on company case studies; and *iii)* the implications for science, technology and innovation policies.

OECD, (2008). *Pharmacogenetics: Opportunities and Challenges for Health Innovation and Care*. (Forthcoming). [DSTI/STP/BIO(2006)36/REV1] STI/BIO.

> Pharmacogenetics offers new ways of understanding how drugs work and how this affects both their safety and efficacy in individuals. The potential opportunities for both drug development and clinical care are considerable. In drug development, pharmacogenetics can improve both the research and development process and the quality and efficacy of the products delivered. Pharmacogenetics can help identify those individuals most likely to benefit from a therapy, optimising treatment strategies for both common and complex disorders. Research in pharmacogenetics is proceeding rapidly. A number of scientific, regulatory, and economic challenges need to be overcome if pharmacogenetics is to be taken up more widely by healthcare systems. This report examines the challenges facing pharmacogenetics at different stages in the health innovation cycle and in the clinic. The report concludes that governments have a role to play in creating an "enabling" environment for pharmacogenetics. In particular it argues that building infrastructures for large-scale association studies is necessary to identify and validate the biomarkers that underpin the use of pharmacogenetics. This publication is based on commissioned consultant papers and an expert workshop.

OECD, (2008). *Emerging Research Models for Biomedicine and Health Innovation.* (Forthcoming) [DSTI/STP/BIO(2007)10/REV1] STI/BIO.

> This report takes a systemic view of innovation systems. It identifies four different approaches to improving the translational research process, all of which share the objective of facilitating the process of discovery research, development and delivery and of bringing biomedical innovations from invention to market faster. The report presents four examples initiatives (Innovative Medicine Initiative, Top Institute Pharma, MaRs, etc.) The report asks: (1) How do these initiatives differ from traditional approaches? (2) Are disparate initiatives and approaches above part of a movement toward the development of a/or several new research and business models that could revive drug discovery and health innovation? (3) What will make the emergence of such new business models possible? The report also identifies measure governments can take to influence health innovation processes and facilitate the development and diffusion of needed new products and services.

OECD, (2006). *Innovation in Pharmaceutical Biotechnology: Comparing national innovation systems at the sectoral level.* STI/TIP, http://www.oecd.org/dataoecd/29/59/36446831.pdf

This report is based on 8 country studies (Belgium, Finland, France, Germany, the Netherlands, Norway, Japan, and Spain). It describes the structure and dynamics of national biopharmaceutical innovation systems in each country and their capacity to develop, produce and deliver biopharmaceutical products and services. It identifies the factors which influence different business models: (1) the openness of innovation systems -- trade, alliances, foreign ownership, (2) demand side factors -- size and configuration of lead markets, type of health care systems, ethical consideration, (3) framework conditions – financial, regulatory, employment, (4) the structure and dynamics of the biopharmaceutical business ecosystem, (5) the science base. The Report identifies a number of policy recommendations which are meant to improve the performance of the national systems for pharmaceutical biotechnology

Workshops summaries

OECD, (2008). "Policy Issues in the Development and use of Biomarkers in Health." [DSTI/STP/BIO(2008)30)] STI/BIO, see also expert analytical papers:
http://www.oecd.org/document/48/0,3343,en_2649_34537_39405168_1_1_1_1,00.html

This document presents the outcomes of a workshop in October 2008 about how to improve the development and use of biomarkers in health care. Topics included: data and knowledge sharing for biomarker research; the creation of an evidence base and the clinical evaluation of biomarkers; the regulatory and policy framework for safe and efficient development of biomarkers; and business models for biomarker discovery, development and commercialization. Policy conclusions to governments focussed on how to create a common evidence base for evaluation, business strategies, regulatory and IP challenges, changes to medical practice.

OECD (2007). *Report of the High Level Forum on the Availability of Medicines for Neglected and Emerging Infectious Diseases*. DSTI/BIO and DCD/PCD. [DSTI/STP/BIO(2007)23/REV1, see also DSTI/STP/BIO(2007)6]
http://www.oecd.org/document/45/0,3343,en_2649_34537_39163757_1_1_1_1,00.html

The Noordwijk Medicines Agenda is a summary of the main themes of the OECD High Level Forum. It identifies actions to stimulate R&D and radically accelerate the development and delivery of medicines for neglected and emerging infectious diseases. The NMA calls on governments to demonstrate political leadership and join a range of interested stakeholders to intensify collaborative efforts and promote coherent policies. It underlines the promise of new models for R&D that help overcome failures in the global health innovation system and draw on collaborative mechanisms for access and use of IPRs, as well open innovation approaches for R&D. It discusses collaborative drug development R&D networks and and new financing mechanisms for R&D.

The background papers to the HLF focus on the health needs of developing countries (Sachs and Sachs) and on the different mechanisms that are being proposed to address the dearth of investment, development and delivery of needed new medicines (Kremer and Williams). The later paper details push and pull mechanisms for incentivising R&D in for neglected and emerging infectious diseases such as support for public-private partnerships, global research funds, targeted R&D tax credits, advanced market commitments, patent extensions. If these mechanisms become widespread they will likely influence health industry business models.

Consultant reports

McKelvey, M. (2008). "Emerging business models and institutional drivers." *Bioeconomy 2030.* (Forthcoming), SGE/IFP, http://www.oecd.org/dataoecd/12/29/40923107.pdf

This paper is about biotechnology business models in the human health sector. It describes existing and emerging health biotech business models and some key trends . It touches on the relationship between internal firm resources and external actors. It estimates future investment into private and public R&D. It identifies four external institutional drivers that will influence emerging business models: (1) technological advances; (2) public research and the public-private interface; (3) policy and institutions; and (4) regulation; (5) demand and consumers**.** The report describes what policies are needed for a better balance and harmony across both industry actors and fields of technologies and calls for measures that take into account the sectoral or technological characteristics of biopharmaceutical innovation systems.

Dukes, M.N.G. (2008). "Biotechnology regulation in the health sector," *Bioeconomy 2030.* (Forthcoming) SGE/IFP, http://www.oecd.org/dataoecd/11/14/40926707.pdf

This paper focuses on the study of regulatory systems which are key factors influencing the business models of the health industry. It analyses both existing and proposed regulation of health products emerging from biotechnology in a number of countries. It tries to determine to what extent existing regulatory approaches are adequate in the field of biotechnology, especially with regard to clinical challenges that will emerge as new technologies come on line (e.g. high throughput technologies, tissue engineering, regenerative medicine, cellular therapies, *etc.*) It suggests what sorts of policies may be needed to palliate to the likely regulatory gaps, including changes to intellectual properties protection norms, legal frameworks for data submission, licenses for medical products issued from biotech, and public dialogue on ethics.

Tait, J. Wield, D. Bruce, A. Chataway, J. (2008). "Health Biotechnology to 2030". (Forthcoming, available at http://www.oecd.org/dataoecd/12/10/40922867.pdf) SGE/IFP.

This paper discusses the main factors to influence health care from now to 2030. It describes two scenarios, or possible futures, for health care development and delivery. The first scenario is the virtuous combination of circumstances and actors that are needed to stimulate innovation in health, generate profits and meet consumer demands. The second scenario shows what could happen if the different systems become increasingly dysfunctional with regard to advances in biotechnology and change too difficult to apprehend. The goal of this paper is to determine what behaviours stakeholders in health innovation systems, including governments, should adopt in order more nimbly adapt to the coming changes in medical research and healthcare. Some drivers of change are discussed including: technology and research, industry innovation systems, governments policies and regulation, health care delivery systems, public and stakeholders attitudes, global economics, demography and human resources, climate change, security, development in animal health and their influence on human health care systems.

3. Main messages extracted from the publications above

1. What are the factors pushing for changes in business models?	
a. The framework conditions for innovation	
Innovation in Pharmaceutical Biotechnology: Comparing national innovation systems at the sectoral level	This report tries to characterise the factors that influence the performance of biopharmaceutical innovation systems. While there is no single optimal configuration of the national innovation system leading to superior performance -- and across countries, the structural and dynamic characteristics vary widely – the report identifies the following as important factors: • Demand factors and markets: market size may function as an attraction to industry but it is not necessary conductive to innovation. To stimulate diversification and diffusion of innovative products, decisions to reward product differentiation and products developed for specific niches may be warranted. • The openness of the systems which is a factor of: – Trade openness in biopharmaceutical products – FDI and foreign ownership of firms. – International collaborations • The scientific base of the country. • The influence of incentives and other framework shaped by government policies as regulatory approaches, incentives for industry, etc. • Systemic failures may hamper the functioning of innovation system. These include inappropriate actors in the production, absence of interactions and linkage between parts of the systems.
Biotechnology to 2030	This chapter suggests that health innovations is affected by : – Global scientific advances – The industrial ecosystem – Government policies and regulatory systems – National health care delivery systems – Key actors and advocacy groups Two future scenarios are envisaged: one where the system is resistant to change, another where there is rapid reactivity to the emergence of new technologies and changes in the health innovation. The nature, extent and rapidity of change in health- related bioeconomy will depend on: • New technological developments, how they interact with one another and with prevailing health care systems. • The regulatory systems that evolve to ensure safety, quality and efficacy of new developments. • The response of markets, consumers, patient and health care advocacy groups, and other key actors. To be reactive to changes, key actors in the system must be able to reach a common understanding of the factors driving change and of a range of options open to them, and work together to ensure a transition to a new health-related bioeconomy.

Emerging Research Models for Biomedicine and Health Innovation	The system of drug development is suffering from declining innovation and escalating development costs. Failure or attrition rate in candidate drugs during development is high. The market perceives a pipeline problem which is increasingly reflected in the financial valuation of bio-pharmaceutical companies. Financial pressure coupled decreased productivity of existing product development strategies, is likely to pave the way for an evolution in research and business models.
b. The emergence of new health related biotechnologies	
Emerging Research Models for Biomedicine and Health Innovation	New health technologies, including biotechnologies, are fostering: • The development of new type of drugs, diagnostics and medical devices that are challenging regulatory standards, intellectual property rights, redefining patient needs and business models. • A modification of the behaviours and interactions amongst different actors (public secotor, biotech firms, pharmaceutical firms, regulators) in the health innovation cycle. • A push toward for personalized and molecular medicine, which portends the opening of new area in health innovation and medical care. • The promise of more efficient and effective treatments, and possibly a more efficient system of health innovation. For example through an earlier predictability of safety and efficacy of candidate drugs. • The emergence of common, shared research infrastructures (e.g. HapMap, SNP Consortium, IMI's joint initiatives). • However, to deliver health improvements widely new technologies will have to be accompanied by organisational, infrastructural and regulatory changes throughout the health innovation system.
Biotechnology Regulation in the Health Sector	New health technologies are changing perceptions about both needs and risks. They require flexibility and ongoing watchfulness on the part of actors in the health innovation system as well as adaptability by the regulatory systems.
Emerging Business Models and Institutional Drivers	Biotechnologies create opportunities for modifying business models trough: • The start-up of new business ventures as specialised knowledge suppliers. • The development and expansion of markets, and the take-over of market segments in pharmaceutical and treatment through technological advances. • New R&D investments which demand higher, more visible, and more immediate returns on investment. • The combination and integration of both existing and new technological competencies into novel bundles of goods and services. • The emergence of specialised "medical integrators," who combine distinct elements of scientific and engineering knowledge and apply them to medicine.

c. The changing nature of public-private interactions	
Emerging Research Models	The interaction between firms and public research organisations is a crucial link in the health innovation cycle. A number of case studies detail innovative initiatives which attempt to facilitate the flow of knowledge across the health innovation cycle, and in particular from the public to the private sector. Ultimately the goal is to improve the translation of innovative research findings into marketable products. Some encouraging changes include: • A shift from traditional approaches to safeguarding intellectual property (IP)toward greater networking, outsourcing, sharing. This includes the broader use of collaborative mechanisms for access to IP. This trend could be further encouraged with the development of knowledge markets for the exchange valuable and sometimes proprietary intellectual assets. • Attempts to improve connectivity and feedback loops between actors at different stage of the innovation cycle by either physically bringing actors at different points on innovation cycle (*e.g.* basic and clinical researchers in the Translational Medicine Research Collaboration) or by creating virtual networks for smoother information flow. • New capital models and gap financing initiatives. Attempts are being made to better leverage public sector funding (for example through increased dialogue and proximity amongst potential funders and entrepreneurs, matching public and private funds). There are also attempts to improve valuation and reporting of intellectual assets, as well as the exploration of alternative approaches to forming capital, such as through bond issues or better uses of philanthropic programs, to finance health innovation research programs.
Emerging Business Models and Institutional Drivers	Public research and the public-private interface are expected to provide opportunities for modifying and initiating business models through: • Exploiting public-private linkages, firms need to develop key components like networks and an understanding open access. • Linking into public research on a global scale, which is important because it helps firms to access and sell their specialised knowledge both locally and globally. • Creating business opportunities, through science and technological advances financed by the public sector.
d. The modernization of the regulatory environment	
Emerging Research models	This report identifies initiatives, such as the Innovative Medicines Initiative or the FDA Critical Path Initiative, which recognise the need for streamlining and modernising clinical testing through improved infrastructures, human capital, and clinical trial design and quality. It identifies a need innovators in the health industry and regulators: • To work together earlier and more cooperatively as new technologies emerge. For example, in developing policies that support the use of personalized medicine in producing new therapies and diagnostics. • To identify common goals and objectives. • To make the regulatory process simpler, less burdensome, while guaranteeing patient safety. • To develop uniform and simple bioethics reviews.

Biotechnology Regulation in the Health Sector	Regulatory systems have a crucial role to play in health innovation and health products development and commercialisation. Safety legislation within a country usually follows on from a major accident or incident. For this reason, regulation has been reactive whereas for modern biotechnology the system of regulation has been proactive. Looking forward, it is extremely difficult to suggest in which manner public policy concerning regulatory procedures should proceed on the coming years.
Biotechnology to 2030	Ideally the pharmaceutical industry sector and the regulatory bodies need to take part in any reform processes jointly. The report notes that regulatory systems must change so as to make easier and faster to bring a new drug to market.
e. Demand side factors and the role of consumers	
Emerging Research Models	Health innovation is tightly connected to the provision, uptake and use of new treatments. Therefore, feedback from patients, providers and purchasers is essential in shaping the innovation process. Bench to bedside linkage is essential for accelerating the innovation process and meeting public health needs.
Emerging Business Models and Institutional Drivers	This report states that individuals are taking more and more responsibility for their health care which is going to modify the business models. Patients are "active consumers" of health care products. New business models will react to drivers such as societal trends, public policy and demand. Consumer demand in health care provision is broadly expected to provide opportunities for modifying business models by: • Prioritising efficiency and efficacy at acceptable levels of treatment that can lower the costs (marginal and total) of diagnosis, prediction and treatment. • Expanding major markets due to the demography and lifestyles changes. • Developing pharmacogenetics, personalised medicine and P4 medicine, which will enable emerging business models focused on new bundles of unique services and goods. This also requires the integration of IT, biology and medicine. • Developing direct interaction between individual "users" and "developers", which promotes new development and testing opportunities similar to those observed in open source software.

e. The opportunities arising from the field of global health	
The High Level Forum on Medicines for Neglected and Emerging Infectious Diseases	These papers suggest that a number of innovative financing, research and business models are emerging in the field of global health. The Noordwijk Medicines Agenda, in particular, argues for the strengthening of existing global research networks, increased collaboration of public and private actors, the use of more open innovation tools for access to IP, and the greater involvement of developing country in both research and development of medicines for infectious diseases. Because the markets for new medicines are too small or uncertain to be deemed profitable, IP has proven insufficient to incentivise R&D in infectious diseases of the developing world. Philanthropic and public funding has been channelled via public private partnerships which often operate as innovation networks. Product development partnerships (PDPs) are an innovative and potentially successful model of collaborative R&D that leverage industry investments and foster innovation to increase the availability and accessibility of health technologies. There is also experimentation with other tools such as prizes, advanced market commitments, patent extensions and buy outs. These new models for promoting innovation and stimulating the development of new medicines vaccines and diagnostics are not necessarily limited to a not for profit context. There may be lessons from such low cost, neglected disease drug discovery approaches, for a wider range of niche and segmented disease markets for pharmaceuticals in the developed world

3. What are the policy recommendations?	
Emerging Research Models for Biomedicine and Health Innovation	A number of measures, policies or intergovernmental cooperation are suggested which can **improve the efficiency of translational research**: • Governments may be the only voice that can take a leadership role in championing some of the new directions for health innovation. • Government has a role in creating incentives to develop less invasive, higher quality of life therapies. • Governments can help create a culture of innovation and change by promoting some concrete solutions. • Governments can engage multiple industry players and encourage them to work together to reach their common goal. One example was increased cooperation in conducting critical but common activities, such as toxicology testing in clinical trials. • Governments have a role to play in educating the next generation of researchers needed, especially in fields such as clinical research and medicinal chemistry. • Governments have a role in identifying and addressing financing gaps. They could explore alternative approaches to forming capital, such as through bond issues or better uses of philanthropic programs, to finance health innovation programs.

Biotechnology Regulation in the Health Sector	The **regulatory environment that supports biotechnology development** must be sufficiently flexible to handle most, though not necessary all, of new technologies, but with some reservations: • The growing importance of biotechnology in the health field may create a need for some supplementary provisions in law (*e.g.* tissue engineering and gene therapy). • Within existing regulatory systems, flexibility may be called for applying existing rules. • Biotech regulation cannot be contained within national borders, international harmonisation may be needed. • Some developing countries may not have either the resources or experience needed to deal with new biotechnologies. • It is desirable to have adequate routes for public consultation in order to avoid public mistrust in scientific institutions and new discoveries. • Direct consumer advertising of innovative medicines may need to be debated. • A balance needs to be found such that barriers to scientific research are not unduly created. • Biotechnology product standards should be the subject of consultation between relevant authorities and industry.
Biotechnology to 2030	In order to assure adaptability and flexibility of the different organisations involved in health innovation, the following recommendations refer to ideal **mix of actors and change implementers** for required: • The need of senior influential thinkers and able to implement change if needed in their organisations. • Representation of such thinkers in policy making from the most important categories of organisations. • The presence of an apparently non-threatening outsider with relevant experience to contribute to the design of new types of organisation, but who is not seen as a competitor for any organisation involved. • A determination from the beginning that the outcomes of the discussions and negotiations will be implemented and a clear route to implementation.
Innovation in Pharmaceutical Biotechnology	This paper argues that **governments have a role in improving international competitiveness** for biopharmaceutical research organisations. Based on the study of the different biopharmaceutical innovation systems the following policy recommendations emerge: • *Coherent and consistent innovation policies:* Combine objectives such as improving international competitiveness through biopharma innovation policies on the one hand and a high quality and affordable public health care system on the other hand. • *Public governance:* Facilitate a more active role of patients and/or their organisations in innovation processes, clinical trails and market access; important sources of innovations remain unused until so far. • *Promoting cooperation and networking:* Create network links throughout the biopharma innovation system, especially between actors in the sciences and the business system. • *Support for an innovative industry:* Develop instruments that provide incentives for private financers to invest in new and young biopharma firms.

	• *Regulatory framework:* Develop transparent and stable regulations, with short application procedures and good information supply on procedures and the development of an adequate system for protecting biopharma innovations. • *Technology transfer:* Stimulate the exploitation of public sector biopharma research, include IPR indicators in review and evaluation procedures, install qualified supportive infrastructure for start-ups (legal, business, marketing expertise, incubator and technical facilities). *Stimulate sound science systems.* The market imperfections associated with basic research still persist, which provides a role for governments' research policies and funding.
Emerging Business Models and Institutional Drivers	Public research and public-private interfaces, technological advances, public policy, institutions and regulation, demand and consumers in health care provision are expected to provide opportunities for modifying business models. This chapter argues that policies must **strike a balance between the interests of different actors**, including industry and public research organisations. The possible trends with implications for public policy are: • Creating business opportunities through research projects financed by the public research sector. • Developing networks and open access. • Modifying institutional structures and ownership of intellectual property rights, for entrepreneurship in public research organisations. • Differing regulatory frameworks, the way actors work together, and the choices taken within the health system will influence which countries "lead" in the new biotechnology. • Developing outsourcing, fragmentation and integration across the value chain.
The High Level Forum on Medicines for Neglected and Emerging Infectious Diseases	The Noordwijk Medicine Agenda proposed a large number actions meant to improve the availability of medicines for neglected and emerging infectious diseases through **increased global R&D capacity and better R&D efficiency**. Policy suggestions included: • Facilitating the use of more open innovation tools. • Exploring the utility of collaborative mechanisms for access and use of IPRs and the application of open innovation tools for R&D in neglected infectious diseases. • Exploring of the different policy tools and financing mechanisms to promote innovation in infectious diseases (*e.g.* Advanced Market Commitments, Prizes, new R&D funds, patent extensions and buyouts). Evaluating the effectiveness of such instruments for promoting R&D and developing needed new health products. • Exploring what support or infrastructure needs for research networks, including public private partnerships. • Exploring whether such networks for product development is influencing industries strategies and business models more generally. • Support the development of regulatory frameworks for biotechnologies and associated medical products that are adapted to developing countries and their health issues.

III. MODULE 3 – THE GOVERNANCE OF NEW RESEARCH AND HEALTH INFRASTRUCTURES

1. Explanation of the policy issue

Biological and health information research infrastructures are important resources that underpin all biological science. They provide information and source material for scientific investigation, and underpin many of the discoveries on which biotechnology is founded. The WPB has extensive experience in the development and promotion of governance infrastructures needed for fostering research in the life sciences and especially for removing the disincentives to the sharing and use of data, knowledge and technologies. OECD work supports Countries in their efforts to establish and maintain research infrastructures; to ensure quality, security, accessibility of the data and materials contained therein; to build public trust and understanding of these infrastructures; and finally to ensure they adequately address policy concerns. Notably the OECD has established Best Practice Guidelines on Biological Resource Centres and is in the process of negotiating a Recommendation on Human Biobanks and Genetic Research Databases.

This module identifies lessons learned about how to set up new organizational arrangements, infrastructures, and governance systems that facilitate knowledge creation, access and use. It identifies challenges such as the difficulty of collective action, and the need for interoperability of data and the promotion of innovation at the interface different disciplines.

2. Related work done by the OECD (in this module the publications are grouped by theme)

Instruments

OECD, (2007). *OECD Best Practice Guidelines for Biological Resource Centres*. *DSTI/BIO.* http://www.oecd.org/dataoecd/7/13/38777417.pdf

See also: *Guidance for the Operation of Biological Resource Centres: Part 1 - General Requirements for All BRCs* and *Guidance for the Operation of Biological Research Centres: Certification and Quality Criteria for BRCs.* www.oecd.org/document/36/0,3343,en_2649_34537_38777060_1_1_1_1,00.html

The Guidelines and supporting documents address the establishment, management and governance of BRCs. BRCs are considered to be one of the key elements of a sustainable international scientific infrastructure necessary to underpin the delivery of benefits of biotechnology, whether within the health, industrial or other sectors. BRCs are repositories and service providers of the living cells, organisms, genomes, and information relating to heredity and the functions of biological systems. Such biological resources provide the source materials for scientific investigations. Ensuring the proper maintenance and supply of biological resources is essential. Four sets of best practice guidelines are described here, dealing with *(i)* general quality aspects, *(ii)* biosecurity-related issues, *(iii)* specific guidelines for BRCs holding and supplying microorganisms, and; *(iv)* specific guidelines for BRCs holding human-derived materials. The best practice guideline for BRCs target quality assurance issues that should be addressed to ensure the supply of high quality materials. In order to improve BRC quality assurance, the CSTP agreed the BRC Best Practice Guidelines in 2007.

Reports for Committees:

OECD, (2008). "Policy Issues in the Development and use of Biomarkers in Health." [DSTI/STP/BIO(2008)30)] STI/BIO, see also expert analytical papers: http://www.oecd.org/document/48/0,3343,en_2649_34537_39405168_1_1_1_1,00.html

This document presents the outcomes of a workshop in October 2008 about how to improve the development and use of biomarkers in health care. Topics included: data and knowledge sharing for biomarker research; the creation of an evidence base and the clinical evaluation of biomarkers; the regulatory and policy framework for safe and efficient development of biomarkers; and business models for biomarker discovery, development and commercialization. Policy conclusions to governments focussed on how to create a common evidence base for evaluation, business strategies, regulatory challenges, changes to medical practice.

OECD, (2008). "Draft Recommendation on Human Biobanks and Genetic Research Databases." [DSTI/STP/BIO(2008)23/REV1] STP/BIO

The WPB is developing Council Guidelines on human biobanks and genetic research databases (HBGRDs). The establishment, harmonisation and broad use of research involving data and samples from human biobanks and genetic research databases analysed in conjunction with personal or health data is important for research and will be increasingly important for not only for healthcare but also for drug discovery. HBGRDs are structured resources that can be used for the purpose of genetic research and which include: a) human biological materials and/or information generated from the analysis of the same; and b) extensive associated information. The draft Guidelines are intended to assist governments in the development of policies applicable to HBGRDs and to provide guidance for private and public sector HBGRDs. The Guidelines, developed by a group of member country experts, cover the establishment, governance, management, operation, access, use and discontinuation of HBGRDs. They also cover governance structure and oversight mechanisms; privacy and confidentiality; terms of participation; access; funding mechanisms; benefit sharing, intellectual property and commercialisation; protection and security of human biological materials and data; the qualifications, education and training of staff; disposal of materials and data and the discontinuation of a HBGRD.

OECD, (2007-2008). *Creation and Governance of Human Genetic Research Databases*. STI/BIO http://www.oecd.org/dataoecd/61/29/37647338.pdf & http://www.oecd.org/dataoecd/61/29/37647338.pdf

This book summarises the proceedings of a 2005 conference on human genetic research databases. Large-scale study of populations may contribute significantly to science's understanding of the complex multi-factorial basis of disease and to improvements in prevention, detection, diagnosis, treatment and cure. The book examines what these databases are and provides a number of examples. It looks at how they have been established, governed, and funded. And it looks at how they are managed and commercialised, exploring what the policy implications are for governments. The book identifies the international policy challenges associated with the establishment, management and governance of human genetic research databases.

OECD, (2008). *Pharmacogenetics: Opportunities and Challenges for Health Innovation and Care*. (Forthcoming). [DSTI/STP/BIO(2006)36/REV1] STI/BIO.

Pharmacogenetics offers new ways of understanding how drugs work and how this affects both their safety and efficacy in individuals. The potential opportunities for both drug development and clinical care are considerable. In drug development, pharmacogenetics can improve both the research and development process and the quality and efficacy of the products delivered. Pharmacogenetics can help identify those individuals most likely to benefit from a therapy, optimising treatment strategies for both common and complex disorders. Research in pharmacogenetics is proceeding rapidly. A number of scientific, regulatory, and economic challenges need to be overcome if pharmacogenetics is to be taken up more widely by healthcare systems. This report examines the challenges facing pharmacogenetics at different stages in the health innovation cycle and in the clinic. The report concludes that governments have a role to play in creating an "enabling" environment for pharmacogenetics. In particular it argues that building infrastructures for large-scale association studies is necessary to identify and validate the biomarkers that underpin the use of pharmacogenetics. This publication is based on commissioned consultant papers and an expert workshop.

OECD, (2007). *"*Intellectual Property Rights in International R&D Collaboration: Background and issues*."* [DSTI/STP/TIP(2007)20)] STI/TIP

This report describes the potential barriers to IP in international collaboration in R&D and innovation. It tries to provide solutions for improving intellectual property and knowledge sharing, such as by placing IP in the public domain, developing patent pools, developing patent portfolio, developing copyright licensing models, *etc.*

3. Main messages extracted from the publications above

1. Why are these research and health infrastructures crucial for innovation in biomedicine?	
BRCs	BRCs are: *"an essential part of the infrastructure underpinning biotechnology. They consist of service providers and repositories of the living cells, genomes of organisms, and information relating to heredity and the functions of biological systems. BRCs contain collections of culturable organisms (e.g. micro-organisms, plant, animal and human cells), replicable parts of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms cells and tissues, as well as data bases containing molecular, physiological and structural information relevant to these collections and related bioinformatics. BRC must meet the high standards of quality and expertise demanded by the international community of scientists and industry for the delivery of biological information and materials. They must provide access to biological resources on which R&D in the life sciences and the advancement of biotechnology depends".* By making available biological materials and information of guaranteed identity and quality, BRCs serve an essential infrastructural function for scientific investigation and R&D. The reliability of biological resources is as important as the purity of chemical reagents and the precision of equipment used to conduct scientific research. The availability of known, validated and precisely identified biological resources is thus essential for research. BRCs are also essential sources of information and materials for industrial and many other practical uses. BRCs have a role in: • Preservation and provision of biological resources for scientific, industrial, agricultural, environmental and medical R&D and applications. • Performance of R&D on these biological resources.

	• Conservation of biodiversity. • Repositories of Biological Reference Material. • Repositories of biological resources for the protection of intellectual property. • Resources for public information and policy formulation. • Raw materials for the advancement of biotechnology, human health, and research and development in the life science.
HBGRDs	Human Biobanks and Genetic Research Databases are defined as structured resources that can be used for the purpose of genetic research and include: • Human-derived biological materials and/or information generated from the analysis of the same; • Extensive associated information. Genetics is key for medical research and the development of innovative diagnostics and therapies. HBGRDs are intended to: • Foster research • Store resources comprising the collection of samples and information • Make data and materials rapidly and widely available to researchers so as to advance knowledge and understanding • Contribute to our understanding of the etiology of complex, multifactorial disease (for example interaction of genetic and environmental factors) and thus improve understanding of drug reactions as well as the detection, prevention, diagnosis, treatment and cure of diseases • Improves scientific capacity to use these vast amounts of knowledge by bringing together of different strands of information and data within databases
PGx	Pharmacogenetics offers new ways of understanding how drugs work and how this affects both their safety and efficacy in individuals. Pharmacogenetics shows great potential for improving the efficiency in the drug discovery process, particularly for identifying and validating new drug targets. Pharmacogenetics is being employed to optimise treatment strategies for common and complex disorders of public health relevance and more effective interventions to prevent disease or illness. But the value of pharmacogenetics is heavily dependent on the identification of useful biomarkers, indicators that mark the presence of a potential gene-drug interaction or that measure response to therapeutic activity. The identification of biomarkers and the establishment of their clinical validity are critical for pharmacogenetics to achieve maximum research, industrial and clinical impact. Identifying and ultimately validating biomarkers requires integrating genetic and genomic data with phenotypic data, which can be both difficult and time consuming. Such association studies usually involve doing clinical studies with a large number of patients, often from a variety of population groups. To carry out the required large scale association studies, appropriate frameworks, systems and methodologies must be established. These are the research infrastructures required to advance the use of pharmacogenetics.

2. What are the gaps in those infrastructures?	
BRCs	The challenges to the development, expansion and survival of BRCs include: • Funding uncertainties that threaten stability • Intellectual property rights • Constraints on access to biological resources within countries and across international borders • Import/export regulations • Lack of adequate quality assurance • Safety issues • Ethical concerns about the uses of genes and other biological resources • Keeping up with the technological advance and the molecular revolution (i.e. genomics and the information revealed by DNA sequencing)
HBGRDs	The challenges to the establishment and development of HBGRDs include: • Financial and human resources: high expenditures required from public sources as well as private sources require assessments of financial feasibility • The need to adhere to applicable domestic law and international instruments: HBGRDs must be established, governed, managed and used in accordance with these • Privacy and confidentiality: the HGBRDs must respect human rights and freedoms and secure the protection of privacy and the confidentiality of data. • Potential for harm: the HGBRDs must minimise risks to individuals, their families and potentially identifiable populations or groups whose specimens and data are included in the HBGRD and used for research. • Public understanding: the purpose of HBGRDs must be clearly formulated and communicated as early and as widely as possible so as to gain public trust
PGx	There are gaps in the incentives for: • Large scale association studies (e.g. the the appropriate frameworks, systems and methodologies) which are necessary to identify and validate genomic biomarkers. • Prospective studies to apply pharmacogenetics to established medicines to identify genetic markers for patient stratification. The costs of such trials could be high.

3. What are the objectives of the Guidelines and the role of the OECD?	
BRCs	Countries asked the OECD to develop BRC Best Practice Guidelines so as to help centres improve quality assurance of materials found in BRCs. The goal of such Guidelines is to: • Strengthen existing *ex situ* collections of biological data and materials and create collections of new resources, including in non-OECD countries • Facilitate international co-ordination among BRCs by an agreed system of linkage. This should be based upon common technological frameworks and modern informatics that link biological data to biological materials across BRCs • Take into account the objectives and functioning of BRCs when establishing and harmonising national or international rules and regulations • Develop policies to harmonise the operational parameters under which BRCs function, including those governing access to biological resources as well as their exchange and distribution, taking into account relevant national and international laws and agreements • Support the establishment of a global BRC network that would enhance access to BRCs and foster international co-operation and economic development
HBGRDs	Member countries decided that OECD should make efforts to create a policy environment which encourages innovation based on human genetics and that at the same time protects patients' interests. A new set of draft Guidelines are presently being developed to provide guidance on the creation, governance, management and use of Human Biobanks and Genetic Research Databases (HBGRDs) used for purposes of genetic research. The Guidelines are deemed necessary in order to encourage the creation of a wide range of HGBRDs (cross-sectional, longitudinal, large-scale, disease-specific, or population-based). Such data resources will provide platforms for international collaboration on a scale not previously attained. And their scientific exploitation will advance our understanding disease etiology. But it is also understood that wide access to such data for biomedical advances must be balanced by concern for the interests of research participants. Individual participants must be willing to contribute and for that research must respect the participants (and their relatives) and be conducted in ways that uphold human dignity, fundamental freedoms and human rights.
PGx	Looking forward, governments could facilitate large scale association and prospective studies for established medicines by: • Encouraging the formation of multidisciplinary international networks that can increase the efficiency of pharmacogenetic research. • Supporting the creation and utilisation of large-scale human genetic databases (HGRDs). • Considering the formation of public-private partnerships to carry out association studies. • Encouraging agreements relating to the availability of raw data and the sharing of data. • Fostering the developments of systems to manage knowledge and intellectual property so as to support open innovation platforms for pharmacogenetics. Consideration is being given in the 2007-2008 biomarkers project to possible mechanisms and structures for improving the processing and sharing of data and information coming from biomarker research in order to facilitate the creation of a base of evidence for establishing the clinical validity of biomarkers more generally.

4. What are the solutions provided by the OECD?	
BRCs	The Best Practice Guidelines agreed by OECD countries address: • Authenticity of biological materials, databases and bioinformatics and accuracy of labeling • Assurance of long-term stability and quality control of cell cultures, cell lines, and genetic constructs, including procedures and standards • Accuracy of the data collected and supplied • International unified quality management/quality assurance • Human resource expertise, particularly of a new generation of taxonomists able to use molecular techniques and informatics • Potential for sharing of expertise among centres through co-ordination and networking
HBGRDs	The draft guidelines cover a broad range of issues important in the creation, governance, management of HGBRDs but are not intended to cover exhaustively all the aspects of HBGRDs. Included in the draft guidelines are Principles and Best Practices which address: • The establishments of HBGRDs; • The governance, management and oversight of HBGRDs; • The terms of participation (by individuals – *e.g.* recruitment, informed consent, rights to withdraw, nature of feedback); • The contents HGBRDs (*e.g.* nature of specimens, quality control, documentation); • The protection of human biological materials and data; • Access (*e.g.* policies of who has access, to what, for what uses) • The qualification, education and training (for HBGRDs personnel); • Custodianship, benefit-sharing and intellectual property; • The demise of the HBGRDs and the disposal of materials and data.

IV. MODULE 4 – THE DEMAND AND TAKE UP OF HEALTH INNOVATIONS

1. Explanation of the policy issue

Governments are searching for opportunities to improve health care and pave the way to high value-added production and services from health technologies. Achieving this requires an adaptation of policies and institutions, including: the regulatory system, the way new technologies are priced/valued, medical practice and health systems, and the alignment of research and health policies.

WPB work in this area has focused on the following set of questions:

- Is there a match between health innovations and public health needs? If not, how can the situation be improved?
- What are the framework conditions or factors that influence incentives for the development of health technologies? And can these be modified to encourage the development of health innovation for the public good?
- How is the demand for health innovation changing and influencing incentives firms face?
- Can one better value health innovations so as to guide investment by innovators and purchasers? What are emerging approaches and methodologies?
- Do innovations improve health outcomes and the quality of health care?
- How does innovation impact health expenditures?
- What are the barriers in the health system receiving environment to the uptake and diffusion of more efficient and effective health technologies? And how can these be addressed to improve the diffusion of efficient and effective health technologies?
- How are new technologies influencing the operation of health systems? What are their impacts on human capital and other resources?
- What are the opportunities and challenges for assessing the effectiveness of innovative biomedical products/processes?

2. Related work done in the OECD

Instruments

OECD, (2007). *Guidelines on the Quality Assurance for Molecular Genetic Testing*. DSTI/BIO
http://www.oecd.org/dataoecd/43/6/38839788.pdf

The Guidelines address genetic testing for variations in germ line DNA sequences or products arising directly from changes in heritable genomic sequences that predict effects on the health, or influence the health management, of an individual. They focus on molecular genetic testing for the diagnosis of a particular disease or condition and predictive genetic testing often carried out before any clinical signs of the disease or condition appear. They are also relevant to tests for heritable DNA variants that predict the response profile of an individual to a drug or course of therapy and that affect susceptibility to disease, patient prognosis, counselling, treatment and family planning. They do not address testing carried out only for research purposes.

Guidelines focus on the provision of clinical genetic services, in particular on: quality assurance systems for the tests offered, result reporting requirements, proficiency testing of laboratories performing tests, and the education and training standards for laboratory personnel.

Reports to Committee

OECD, (2008). *Pharmacogenetics: Opportunities and Challenges for Health Innovation and Care*. (Forthcoming). [DSTI/STP/BIO(2006)36/REV1] STI/BIO

Pharmacogenetics offers new ways of understanding how drugs work and how this affects both their safety and efficacy in individuals. The potential opportunities for both drug development and clinical care are considerable. In drug development, pharmacogenetics can improve both the research and development process and the quality and efficacy of the products delivered. Pharmacogenetics can help identify those individuals most likely to benefit from a therapy, optimising treatment strategies for both common and complex disorders. Research in pharmacogenetics is proceeding rapidly. A number of scientific, regulatory, and economic challenges need to be overcome if pharmacogenetics is to be taken up more widely by healthcare systems. This report examines the challenges facing pharmacogenetics at different stages in the health innovation cycle and in the clinic. The report concludes that governments have a role to play in creating an "enabling" environment for pharmacogenetics. In particular it argues that building infrastructures for large-scale association studies is necessary to identify and validate the biomarkers that underpin the use of pharmacogenetics. This publication is based on commissioned consultant papers and an expert workshop.

OECD (2008). "Chapter 6. The Impact of Pharmaceutical Pricing Policies on Pharmaceutical Innovation". *Pharmaceutical Pricing Policies in a Global Market.* DELSA/HEA
http://www.oecd.org/health/pharmaceutical

Pharmaceutical pricing policies are designed with national objectives in mind, but are the transnational implications always taken into account? This report assesses how pharmaceutical pricing and reimbursement policies have contributed to the achievement of certain health policy objectives. It examines the national and transnational effects of these policies, in particular, their implications for the availability of medicines in other countries, the prices of these medicines, and innovation in the pharmaceutical sector. This publication presents an analysis of comparative price levels, making use of a unique dataset to construct the most comprehensive pan-OECD pharmaceutical price index to date. It also draws upon original case studies of pharmaceutical pricing and reimbursement policies in six OECD countries to provide specific examples of the impacts of policies on health system performance. Chapter 6 focuses on pharmaceutical R&D investment and the ways in which pricing and reimbursement practices contribute to trends in innovation.

OECD, (2008). *"*Health ICT Use and Adoption: Case studies.*"* [DELSA/HEA(2008)1] DELSA/HEA

This is an ongoing project which will end in 2009. It aims to provide OECD governments with advice concerning a range of policy options, conditions and practices that may help achieve efficiency improvements in the health sector through more widespread adoption of ICTs. There are two work streams to identify and analyse: i) the most common indicators used across OECD countries for benchmarking the use and adoption of ICTs; and ii) drivers and incentives for ICT adoption within the health sector. The study includes a synthesis of information in the published literature and in national studies, and a more focused set of in-depth case studies in selected countries.

OECD, (2008). *"*Uptake and Diffusion of Health Related Biotechnologies*"*. [DSTI/STP/BIO(2005)22] BIO. (Forthcoming) DSTI/BIO

This report is based on a paper by a consultant. It discusses five health-related biotechnologies and identifies the range of incentives and barriers that affect their uptake and into the health care sector. The selected technologies differ in their stage of development, including innovations that are relatively mature to those that are still very new, but all have products on the market. The five case study

technologies are: monoclonal antibodies as diagnostics and as therapeutics; molecular genetic testing; DNA micro-arrays; and the convergence of bio- and nano-technologies. For each technology, the report identifies the potential clinical utility and the factors identified through a literature survey that appears to be either stimulating or inhibiting its diffusion into the market and eventually the health care system.

OECD, (2007). *"*Promoting Innovation, Promoting Health.*"* [DELSA/HEA(2007)8]. DSTI/BIO & HC

This document is based on expert interviews by a consultant in eight OECD countries about how each country is approaching the challenge of delivering greater convergence between healthcare priorities and health innovation. The purpose was to explore how to better meet the dual policy objectives of investing in and encouraging innovation while maintaining the affordability, quality and sustainability of healthcare systems. The study, which includes seven country chapters, discusses how various governments, government departments and other actors define innovation in health care; it documents key government programs to promote innovations which meet public health needs; it identifies initiatives that coordinate health care and innovation policies and discusses motivations behind such initiatives.

OECD, (2005). *Health Technologies and Decision Making*. STI/BIO
http://www.oecd.org/document/55/0,3343,en_2649_34537_35589431_1_1_1_1,00.html

This publication focuses on the policy challenges around how to encourage the uptake of the most efficient and effective health-care technologies. The study is based on an eight country survey of decision-making processes for 5 technologies. Comparative information was collected on decision-making processes for five case study technologies: positron emission tomography, hepatitis C genotyping and viral load testing, telemedicine, prostate cancer screening, and technologies for dealing with stroke patients. The focus of the study is on how evidence, primarily in the form of health technology assessment (HTA), was produced and subsequently used in decision making. In terms of policy, it considered options for dealing with uncertainty in the evidence base, consideration of the transferability of evaluations between different situations, and analysis of how biomedicines challenge decision makers.

Workshops

BIAC, (2007). "A Turning Point for ICTS in Health Care? Key Points from the BIAC–LMP Consultation.*"* [BIAC PAC/AFF/LMP(2007)3].

The Business and Industry Advisory Committee (BIAC) convened an expert group in November 2007, which included leading representatives for doctors, patients, health programs, the employers, the pharmaceutical industry and ICT system providers. The group was asked to discuss ICTs in health care in November 2007, and specifically addressed: What is the status of ICT in health care today? How is the market evolving? What challenges lie ahead? And, which new business models are emerging? The second paper presents a summary of the conclusions from this meeting.

OECD, (2005). *"*Biomedicine and Other Innovation in Healthcare: Examining the Links Between Policymakers and Innovators.*"* [DSTI/STP/BIO(2005)12/REV1] STI/BIO

This report is a summary of joint WPB/Group on Health workshop which, *inter alia*, identified the need for improved alignment of innovation and health care policies. The workshop explored how to improve the successful delivery of biomedicine and other health innovations. Participants discussed how to deliver greater convergence between health care needs and innovation; what tools need to be developed to ensure that health care decisions more fully capture the benefits of innovation and

contribute to fostering future innovation; and what improvements to policy-making could ensure that efficient and appropriate innovations diffuse into health systems.

3. Main messages extracted from the publications above

1. What are the barriers and constraints that impede the process of uptake and diffusion of new technologies?	
Health Technologies and Decision Making	The rational use of evidence developed through health technology assessment (HTA) depends, in large part, on the decision making process and on the institutional, organisational, political and cultural dynamics of health care systems. • Diffuse decision making structures at multiple levels of the health care system make it difficult to implement the results obtained through HTA. • The challenge for many policy makers is to develop policy tools that aim to achieve multiple health system goals simultaneously. • The institutional and financial aspects of the health system have a crucial influence on whether decisions will be successfully implemented. • Decision makers often face difficulties in determining whether the results of economic evaluations, which may be carried out elsewhere, are relevant to their own local circumstances. • For some technologies, the pace of development tests the capacity of HTA producers to keep assessments current. HTA producers generally only occasionally undertake assessment updates to keep abreast of research and development, citing lack of resources as the main barrier. • The challenges to HTA from biomedicine relate mainly to speed of development of biotechnology, investment risks and returns, potential high cost and high effectiveness, and ethical as well as public perception considerations.
Promoting Innovation, Promoting Health	• Understanding of what constitutes health innovation is not uniform. Health innovation can include new or improved products or processes that could be marketed in the health sector, as well as reforms or adjustments to the delivery of health care services. • Policymakers have multiple policy objectives with regard to health and innovation policy. Different parts of governments focused on barriers at different aspects of the health innovation cycle. Health ministries tended to be concerned with the welfare of patients and cost containment, whereas economics and research ministries have less ambivalent views regarding the promotion of new health technologies. Several countries raised barriers within the health innovation cycle: • Biotechnology SMEs face pipeline bottlenecks due to difficulty to reach clinical proof of concept • Biotechnology start-ups face difficulties in raising seed capital and financing • Regulatory barriers are an important break on technology transfer • Insufficient development of appropriate, use of private health care that may facilitate uptake and diffusion of innovative products • Networks between industry and public research sectors are typically weak • Recruiting patients for clinical trials is made difficult by their wide distribution, and infrastructures to enrol them is weak • Research funds are often too numerous and small to be effective, and should be consolidated • Patients sometimes lack trust in new medical treatments and devices

Uptake and Diffusion	• Technology often progresses far faster than the institutional mechanisms that are needed support its widespread diffusion and • The regulatory environment for more mature technologies, such as molecular diagnostics, poses pricing problems that inhibit dynamic investment by the private sector and price levels remain above those that would make the technology available to broad segments of the population. • Intellectual property issues can pose potential stumbling blocks to widespread uptake for some technologies, in particular those at the interface of different disciplines (e.g. bio-nano health technologies). • Lack of quality standards, uniform clinical protocols, large-scale population studies and training of clinicians means that clinical and medical practice has not yet adapted to the possibilities offered by the new technologies. • For the least mature technologies, financing gaps may be a stumbling block to further research needed to bring the technology to a commercial stage.
PGx	• The economic incentives to invest in the development of biomarkers are influenced by signals from the broader health care system. Within current pricing and reimbursement mechanisms, the lack of recognition of the value of testing represents a disincentive for the devices industry to develop new, genetics-based assays. • It is crucial to understand the extent to which payers are prepared to award higher prices for greater benefit. • The blockbuster model for drug discovery and development poses a potential limitation to the uptake of pharmacogenetics. Most pharmaceutical companies may be reluctant to embrace an R&D approach that could imply both: i) a fragmentation of current large markets; and ii) smaller markets for each individual product.
Pharmaceutical Pricing Policies	• The most difficult trade-off in pharmaceutical policy is the trade-off between static efficiency – in which consumer welfare is maximised by getting the most health value from today's expenditures, as constrained by the limits of present technological capability – and dynamic efficiency, in which the R&D incentives serve to generate growth in the capacity to prevent health conditions and cure diseases in the future. • Pharmaceutical policy making serves multiple objectives that must be balanced with one another to arrive at the policy mix that best reflects national priorities. The objective of ensuring affordable access to effective medicines runs up against strong pressures for public sector cost-containment. • The perceived potential for manufacturers to exploit a monopoly position when facing relatively inelastic demand for medicines has led many countries to regulate prices for at least some portion of the pharmaceutical market. Regulators, public coverage schemes and private insurers have a common arsenal of tools by which to limit the prices charged by pharmaceutical firms or define the level of reimbursement offered to defray households' pharmaceutical expenditures. • Policy makers seek to restrain the rate of growth in pharmaceutical expenditures, although the optimal expenditure level is undefined. • Pharmaceutical pricing policies have been the focus of attention in terms of their impact on pharmaceutical markets, but other types of policies are important in their prospective impact on the timely availability of products in the market, the adoption and diffusion of those products, and the level of consumption of the product over its life cycle. Chief among these policies are those that affect market authorisation and those that set standards for enforcement of intellectual property rights. In addition, coverage schemes routinely employ policies aimed at patient demand (in particular, cost-sharing requirements), often employ policies aimed at pharmacists' dispensing (such as policies to promote use of generic alternatives to off-patent original medicines), and occasionally employ policies aimed at physician prescribing (*e.g.,* prescribing budgets).

Health ICTs	The Committee on Health's project raises the following challenges: • Access to appropriate baseline technology (e.g. internet connectivity available to individuals and communities) and interoperability represent the most difficult issues for enhancing the dissemination of e-health applications. • Data security and privacy of personal health data remain high-priority issues. Electronic health records include patients' sensitive health information. Accidental or unintentional release of this information may present a risk of serious harm to an individual. • The application of legal rules and ethical imperatives regarding informed consent to the collection, use and disclosure of personal health information has proven, particularly challenging in the context of electronic health records. • Financial benefits have been hard to determine in order to justify in terms of cost-benefit analysis the implementation of information systems. • The BIAC Expert Group raised a complementary set of issues: • There remains a misalignment of incentives between who pays and who benefits from ICT in health. • Other economic challenges include: a resistance to pay-for-performance programs, difficulties financing ICT systems, and an inability or unwillingness to replicate best practices that impede the creation of a market for standardized ICT products and services. • People, processes and change management pose greater obstacles than technology for implementation. For example, the effort to transform the ways physicians and health professionals work has globally been met with stiff resistance. • There are dangers inherent in storing sensitive medical information of citizens. An emerging challenge is coming to widely held concepts of security, privacy and confidentiality.

2. What practices and policies foster demand for and take up of innovation?	
Health Technologies and Decision Making	• The process of health technology assessment (HTA) is widely regarded as able to deliver succinct, high quality and trusted evidence to decision makers at all levels of the health care system. And many OECD countries are developing and implementing policies to support the production and improvement of the range of approaches and methodologies involved. • Improved communication: A number of initiatives can improve communication of the results of formal assessment to a broad range of decision makers and stakeholders, such as policy makers, clinicians, industry and patients. A "portfolio" approach to dissemination may be more effective than any single approach to disseminating the results of HTA analysis. • Some OECD countries try to develop a "culture" of evidence based policy and practice by stimulating activities that generate greater demand for HTA, including education programmes targeted at developing decision makers' skills in interpreting and analysing evidence, establishing information infrastructure to make evidence more readily available and developing decision-making processes with a more clearly defined role for HTA. • Technology assessment largely needs to be tailor-made for the policy questions to be answered and linked more comprehensively with innovation and other aspects of policy making. • Decisions about the uptake and diffusion of health technologies take place at multiple levels of the health care system. Where clear decision-making structures existed, the impact of HTA evidence on decisions seemed to improve, perhaps because HTA practitioners were better able to direct their assessments to pre-defined target groups. • Decisions about health technologies are more likely to be accepted by stakeholders if the decision making process is regarded as transparent and based on evidence, and if it includes an appeals mechanism.

	• The level of stakeholder trust in the evidence, and in the systems that use it, emerges as a key determining factor. • The problems of applying technical information to policy can be reduced if there are formal linkages between users and producers of HTA. Formal HTA liaison or management infrastructure within ministries can foster knowledge and expertise within the administrative arms of governments. • HTA must be tailored to individual characteristics of the health-care system, including consideration of where decisions about uptake and diffusion of technologies get made.
Promoting Innovation, Promoting Health	• Country respondents identified a variety of priority policy areas for health innovation that may be broadly categorized as concerns in the areas of health research, health services and priority diseases. • Health research: Enhance involvement of clinicians in the activities of public research institutes; and Improve technology transfer and development of commercial applications. • Health services: Improve the quality of services offered; Contain Costs; Strengthen clinical human resource capacity; Provide timely and equitable access to needed care • Country respondents also identified a range of policy tools being used to improve health innovation, including: • Direct financial support • Improvements to the business environment • Facilitate commercialization of health research • Promote collaborative initiatives between stakeholders • Refinements to the regulatory framework to facilitate cost containment • Reforms to health care services • Leveraging the education system
PGx	• Regulatory authorities have a clear interest in seeing the benefits of pharmacogenetics applied to both new and existing medicines. Moreover, they are in a position to influence the introduction of pharmacogenetics as a tool that will benefit human health and support innovation. The development of transnational regulatory approaches and policies, coupled with efforts to close existing gaps in relevant practices, can only increase this influence. • One objective of such transnational dialogue could be to achieve consensus on the process by which regulatory authorities choose to approve and validate pharmacogenetic tests for a drug or to modify a label. Such transnational dialogue is also required concerning the related but distinct issues around economic and other health technology assessment, and post-marketing coerage and reimbursement decisions. • To encourage clinicians to include pharmacogenetic biomarkers in the range of tests they normally apply several things must happen. First, the tests must be made available in a timely, reliable and recognised form, and must give clinically useful, reproducible results that can be readily interpreted and understood. Second, clinicians must be aware of and properly informed about the tests – both their benefits and limitations. There is a need to educate physicians so that they remain up to date in a rapidly changing field. • Patients and patient groups could be influential in driving the demand for pharmacogenetic tests and medicines. Patients are increasingly well informed about the genetic component of disease and the options for testing, diagnosis and treatment regimes. They are also aware of the availability of new medicines, including targeted drugs. Patients want the best medicine for their condition: their decision-making strategies include a willingness to consider the risk/benefit equation of a medicine.

Pharmaceutical Pricing Policies	• Out-of-pocket payments are relatively important sources of financing for pharmaceuticals. • When a drug is in a real monopoly position in a therapeutic area and is used in the treatment of a life-threatening disease, both public and private purchasers experience public pressure to cover the drug. Profits reward past investment in pharmaceutical R&D and serve as an incentive for future investment. But prices are not the only factor determining profits. • As in other industries, private R&D investment in the pharmaceutical industry is motivated primarily by expected returns on the investments, given scientific opportunities (the state of the art in a therapeutic area or in a mode of production) and the comparative advantages of firms. The pharmaceutical products that make it to market are those that are viewed by the pharmaceutical industry as most likely to be profitable in terms of the conditions they target and the level of innovation they represent over existing alternatives.
Quality Assurance for Molecular Genetic Testing	The Guidelines offer Principles and Best Practices which have been agreed by OECD countries as key to improving quality assurance of clinical molecular genetic testing. The Guidelines specifically: • Promote minimum standards internationally for quality assurance systems and molecular genetic testing laboratory practices. • Facilitate mutual recognition of quality assurance frameworks. • Strengthen international cooperation and facilitate, where appropriate, the cross-border flow of samples for clinical purposes in accordance with recognised principles for their handling, storage, safety, privacy and confidentiality. • Increase public confidence in the governance of molecular genetic testing.
Health ICTs	The Health Committee project on ICT has identified some preliminary practices: • ICT initiatives embedded in wider reform efforts aimed at introducing substantive changes into the health sector and in the relationships among health care providers and the roles they perform. • Incentive programmes that target primary-care physicians and have actively engaged physicians in the development and implementation of projects. • The establishment of standards and guidelines that support individuals' rights to control the disclosure of their health information for treatment. The BIAC Expert Group agreed: • National governments hold powerful levers for policy and leadership that would accelerate adoption of ICT for health. • At the enterprise level, enterprise resource planning (ERP) solutions and shared services could dramatically increase productivity, facilitate procurement and human resource management and should therefore be considered as a priority. • Standards for interoperability of ICT: several sets of standards for exchanging data had been adopted worldwide. And one speaker went so far as to say that standards no longer present the bottleneck for implementing ICT health programs. The involvement of patients and users of health ICT systems is essential for developing ICT solutions.

3. Policy needs as articulated by public & private sectors	
Health Technologies and Decision Making	• There is a need to strengthen the analytical enterprise for evaluation, perhaps through new public and private partnerships that enable the costs of health evaluations to be shared. • There remains uncertainty over the extent to which evidence can be transferred from setting to setting. A lack of transparency in reporting means that it is often difficult to assess the relevance of economic evaluations to their local setting, or to extrapolate the results. The development of clear **shared reporting frameworks** could ease this situation. • There is only limited evidence that HTA is effective in terms of its influence on decision making, on health technology use or on health outcomes. More empirical work is required to open the "black box" of decision making to see better how **policy makers use the various tools and evidence available to them**. • The use of "conditional approvals" for the funding/ reimbursement of new technologies by health service providers can provide opportunities to grant access to technologies, while collecting further data to overcome uncertainty and minimise potential risks. Risk-sharing agreements between industry and governments or other health service providers help deal with uncertainty. These include price-volume agreements and/or commitments to gathering further data. Such agreements need to have clearly defined parameters understood by both parties, with clear end points and appropriate opportunities for review. These techniques **require more rigorous evaluation**.
Promoting Innovation, Promoting Health	• Countries perceive health innovation as encompassing one or both of the following: new or improved health-related technologies and quality improvements to the health care system. • Education and human capital formation has an important role to play in fostering the capacity of a country to generate new health-related products, to conduct clinical trials and to meet the demand for high quality health care services. • Countries can create synergies between the output of their innovation policies and objectives in health care by articulating national health priorities, aligning their research and development activities to these and establishing high level political co-ordination between relevant ministries, industry and the medical services community to monitor implementation. • Countries can improve their capacity to translate public research into commercial applications by providing incentives for clinicians to participate in public research institutes, ensuring that funding committees include members with applied research orientation, and by requiring project applications to specify the potential impact of their results.
PGx	The ability to deliver pharmacogenetics depends on three factors: • Broad agreement amongst specialists. • The development of evidence-based guidelines that will contribute to clinical practice and reimbursement decisions. • The development of reimbursement schemes that provide appropriate incentives to various components of the system, allowing for fair financial benefits. Policies could help make the uptake of pharmacogenetics more attractive. Clear signals from governmental and regulatory bodies about how this technology will be priced and reimbursed, recognition of the added value of diagnostic tests for the health system as a whole, and mechanisms for capturing and protecting intellectual property inherent in diagnostic tests might improve the incentives for investment.

	• Coordination **and dialogue with regulatory authorities**: Clarity is required around how regulation will deal with the co-development of diagnostics and therapeutics – both from the perspective of linking data requirements for approvals and from the perspective of how subsequent reimbursement systems will react to co-marketing of co-developed products; as well as on how subsequent reimbursement/coverage decisions might proceed for pharmacogenetic products. • Countries may want to consider the options of **conditional market approvals**, employing post market pharmacovigilance, and risk sharing mechanisms for pharmacogenetic products. • The development of common transnational approaches and policies, coupled with efforts to close existing gaps in regulatory and technology assessment practices across the OECD could also help improve incentives to innovate. • The **health and economic impacts of pharmacogenetics** need to be better understood if the health care system is to adopt new technologies. There is a lack of data that demonstrates the clinical utility and cost effectiveness for many pharmacogenetic therapeutics and diagnostics and no agreement over whose responsibility it is to develop such data. • There may be a need to develop **new health technology assessment models** for the assessment of diagnostics and medicines which could eventually influence the pricing and reimbursement of such products. • **Health care providers will need to be educated** about pharmacogenetic assays and treatment options, and to interpret these assays clinically useful information must be easily accessible to them at the point of care.
Pharmaceutical Pricing Policies	Improvement in meeting public health objectives may well be possible without sacrificing cost control. • **Efforts** to improve value for money in public spending on pharmaceuticals could do a lot to free up resources that could be better spent enhancing the availability, accessibility and appropriate use of effective medicines. They could get better value for their money by maximising the use of generic alternatives to off-patent original products, fostering erosion of the prices of off-patent products through competition, ensuring efficient distribution systems for prescription and OTC products, and becoming more sophisticated in their reimbursement pricing strategies. Pharmaco-economic assessment can help to ensure good value for money in health expenditure. • The most common shortcoming in pharmaceutical pricing and reimbursement policy is a failure to make an explicit assessment of the benefits or expected benefits from a medicine and to use that assessment as a guide as to willingness to pay for (or subsidise) an innovative new pharmaceutical product, taking into account optimal use of the product among the population. Pharmaco-economic assessment, as with health-technology assessment more generally, is a technically challenging and value-laden exercise. Nevertheless, it can be technically and politically feasible when employed in different types of health systems. Pharmaceutical pricing and reimbursement approaches using pharmaco-economic assessment establish incentives for investment in valued innovation. • In the interest of encouraging valuable innovation, efforts to link the level of expenditure for a given pharmaceutical product to the value of the benefits offered by the new product are attractive in that they can be used by manufacturers to assess willingness to pay for future innovations and should thus provide incentives for investment in R&D leading to valued innovation. A tool for evaluating a product's value, relative to its costs, pharmaco-economic assessment can be used to reward and incent innovation with the greatest value to patients and society. To the extent that pharmaceutical producers profit more from innovations that have the greatest value to patients and society, they will face incentives to invest more in R&D to produce such therapies.

Health ICTs	The Health Committee project put forward some preliminary findings: • There is demand for internationally **comparable indicators about ICT use** in health care • There is a need for a better understanding of **financial incentives** to encourage the adoption of ICTs is today both limited in scope and inconclusive. • An appropriate balance must be struck between the patient's rights to restrict the use and disclosure of own health information, and the likely benefits that accrue from having that same information readily available when required for care or for public health action. The key messages coming from the BIAC Expert Meeting include: • Standards for interoperability of ICT, now being adopted consistently, should be further encouraged. • There remains a misalignment of incentives between who pays and who benefits from ICT in health. • The involvement of patients and users of health ICT systems is essential for developing ICT solutions. An emerging challenge is coming to widely held concepts of privacy and confidentiality.