

OECD Project on Pharmaceutical Pricing Policies and Innovation

BIAC contribution to the OECD Expert Meeting 1-2 December 2005

Introduction

As employers that cope with continually increasing health care costs, BIAC members understand and empathise with the challenge facing OECD governments in maintaining balance of their health budgets as they address the expanding social needs of their aging populations, especially in the context of slow or minimal economic growth.

Considering the challenges our health care systems are facing, reforms are necessary. Such reforms have to go beyond cost containment policies or even rationing. Indeed, history shows clearly that governments can achieve better cost management, improved effectiveness and efficiency, as well as greater equity above all as a result of fostering innovation across economic sectors, including access to new products and services. Furthermore, reforms to the funding mechanisms of health care systems are critical to induce efficient health service delivery and reduce the negative effect of rising non-wage labour cost and compulsory health insurance contributions on employment, consumption, competitiveness and overall economic growth. Finally, recommendations for reforms have to be adapted to the specific situation of the wide variety of national health care systems which have developed over time their specific features.

The OECD's expertise in the collection and analysis of economic data, and in the development of policy recommendations derived from that data, makes it a valuable resource in helping member governments improve the performance of their health systems and embark on necessary reforms. BIAC supports the Health Group's objectives of improving the completeness and comparability of the OECD health data file, implementing the system of health accounts, expanding its series of reviews of national health system performance, developing robust indicators for comparing health care quality across OECD countries, and identifying ways to improve efficiency in health care delivery. All of these projects are fully consistent with the mandate given to the OECD by member-country health ministers at the 2004 "Health of Nations" Forum.

The OECD project on "Pharmaceutical Pricing Policies and Innovation" is intended to identify and overcome obstacles to health care innovation through an examination of the cross-national impact of national pharmaceutical pricing policies in OECD countries. As originally proposed by DELSA and approved by the OECD Council, the project seeks to determine "how national pharmaceutical pricing policy decisions affect innovation in the pharmaceutical sector," and whether "policy changes [are] needed to safeguard continued pharmaceutical innovation and to promote innovation that matches national health priorities." It also seeks to determine whether "policy changes [are] needed to ensure that the benefits of innovation are widely available and affordable on a worldwide basis."

Recent work of the OECD Technology and Industry Policy on Case Studies of Biopharmaceutical Innovation has indicated that lack of patient input and inappropriate or

inflexible pricing and reimbursement conditions can create barriers to innovation in many of the examined countries. BIAC fully supports the goals of eliminating regulatory barriers to the development, diffusion, and rapid uptake of new health technologies, and of ensuring that spending on new health technologies achieves maximum efficiency and cost-effectiveness. These reforms should put the safety of the patients at the first place. In the Appendix, BIAC has prepared a list of key studies that have dealt with this complex problem.

Measuring the Impact of Biopharmaceutical Innovation

Innovation, both with respect to products, services and processes, fuels economic growth through enhancements in productivity, a fact demonstrated by numerous OECD research projects. The pioneering work of the OECD shows that a growing share of these innovations come from health-related applications. Thus the agenda for economic growth is closely tied to innovation in life sciences and health and is linked to the ability of producers to rapidly disseminate new technologies. In “Biotechnology for Sustainable Growth and Development” (2004), the OECD recognized the essential role of private-sector R&D in realizing the full benefits of health innovation, and it called for the analysis of mechanisms to strengthen incentives for increased private-sector investment in health and ensure that innovators can gain an appropriate return on their investments.

Many OECD countries have recently sought to attract more R&D investment and, to that end, have developed strategic programs in life sciences. BIAC believes that public policies should support innovation in health care as much as in other sectors. To encourage a conducive policy environment for continued biopharmaceutical innovation, OECD member governments should uphold intellectual property rights, fair reward for new products and processes, and sustainable reimbursement by national health systems of new therapies, especially breakthrough. The implementation of these reforms should take into account the balance of the health insurance system and the impact on non wage labour costs of private companies.

The biopharmaceutical industry makes a significant contribution to the health and wealth of citizens of OECD member states in two major ways. First, the industry develops new medicines, vaccines, and diagnostics that bring significant advances in the prevention, treatment, and cure of cardiovascular disease, asthma, diabetes, HIV/AIDS, cancer, and other major health threats. Innovative medicines and medical devices make possible new and more cost-effective modes of treatment, including cutting-edge surgical procedures. Second, as a major international knowledge-intensive and R&D-intensive industry, the biopharmaceutical sector generates high-value employment and strengthens the science base in countries in which it invests – both directly and through powerful multiplier effects locally and worldwide.

While the positive impact of biopharmaceutical R&D investment on health outcomes, knowledge and wealth creation, and national economic growth and competitiveness is well-recognized, internationally comparable data to demonstrate the contribution of the industry over time and to guide the public policies of individual OECD governments is lacking.

For example, the innovative products of research-based pharmaceutical and biotechnology companies are rarely evaluated in terms of their contribution to medical care and improved health outcomes, since no international organization has attempted such measurement on a continuing basis. Such organizations focus their analytical attention on the costs to payers of innovative health technologies viewed in isolation, rather than on the overall cost savings and productivity increases they make possible. At last year’s ministerial meeting, BIAC encouraged the OECD to undertake such an examination, and the Science and Technology and Health Ministers implicitly supported this call in their communiqués.

Role of Governments in Creating A Conducive Environment for Innovation in Health Care

Successful public policy rests on several core conditions enabling such innovation:

- Efficient and transparent regulatory systems that protect quality and safety, and deliver predictability
- Appropriate and timely access by patients to medical innovation
- Strong standards and effective enforcement of intellectual property protection, and avoidance of measures such as parallel trade and therapeutic reference pricing that indirectly undermine the value of the intellectual property of research-based companies
- Clear, open and predictable pricing systems that provide incentives for continued innovation by encouraging investors and enabling innovators to achieve an adequate return on the investments in the biopharmacy sector.
- Open trade and investment
- Strong and sustainable fundamental research and development infrastructure
- Ethics and rule of law
- Stable and predictable political, financial and legal environment favorable to research and development
- Support for education at all levels

Economic Incentives

Pharmaceutical innovation is costly and risky, and is predominantly carried out by the **private** sector in close collaboration with the public sector. It requires **economic incentives** for which intellectual property protection is a prerequisite. Such protection involves a social agreement, in which innovators are guaranteed the exclusive right to commercialize their patentable innovations for a fixed time period, in return for disclosing product information that will enable competitors to market generic versions following patent expiry, thus bringing down final costs to the consumer. This private-sector model of pharmaceutical R&D has strongly contributed to meeting health needs worldwide. In the relatively rare cases in which private-sector R&D fails to meet specific public health priorities, it might be necessary for governments to provide additional incentives. Orphan drug legislation, for example, has successfully provided incentives for research into treatments for rare diseases by increasing the potential financial returns. Similarly, governments have considered extending patents on treatments marketed primarily in developed countries, in return for increased research by the patent-holder into new therapies to treat genuinely neglected diseases. In addition, patient groups increasingly provide input that is a necessary signal for innovation.

Health care R&D is global and relies on **access** to global markets. Faster and more reliable rates of diffusion and uptake worldwide would help contribute to lower costs to patients. Cost-containment policies geared only to short-term budgetary objectives, by contrast, might raise overall health costs while depriving patients of access to needed treatments.

For example, governments could increase the benefits to patients and alleviate the high costs of medical R&D by adopting policy reforms aimed at reducing the time necessary for market approval. They can achieve this goal, for example, by relying more on information technology in testing for safety and efficacy. Safety of patients remains the first priority of the BIAC healthcare policy taskforce: considering more flexible rules governing clinical trials that could lead to faster market approval and should be effectively subordinated to this priority.

Efficient regulatory systems when applied to pharmaceuticals encourage the constant flow of new products while facilitating competition from generic products following expiration of the originator's patent. Pricing and reimbursement controls often introduce market distortions that artificially distort the financial returns from innovative products and obstruct access to them by patients, while artificially raising the cost to consumers of competing generic products. A more open, predictable and stable pricing system would place a higher value on newer, more effective medicines, thereby encouraging continued innovation, while also facilitating uptake of low-priced generic medicines, thereby serving the interests of consumers, employers and governments.

Pharmaceutical Pricing Policies and Innovation Project

National pricing and reimbursement policies create an ever changing patchwork of local conditions affecting the uptake and diffusion of new products. National price and reimbursement controls are usually established to curb spending on pharmaceuticals. However, long experience tends to demonstrate that controlling prices of pharmaceuticals is not always an effective way to contain overall health spending. The tendency of some governments to view spending on pharmaceuticals mainly from a cost containment perspective leads to frequent changes in regulatory regimes, resulting in an unstable and unpredictable business climate for developers of innovative products. This instability is prejudicial to the overall process of innovation. Price controls impact competitive conditions both in individual countries and across markets, distorting the information about relative value of products. In some cases, such measures can diminish the effective value of patent protection, while also failing to deliver the anticipated long-term reduction in the price of generic products over the product's life cycle. The OECD's project on Pharmaceutical Pricing Policies and Innovation represents an attempt to examine and capture the combined and cumulative international impact of the various national price and reimbursement controls and schemes on the success and extent of health innovation.

In its first stage, the OECD proposes to collect data on pricing policies to create a "taxonomy" of the regulatory regimes that currently exist in OECD countries. The stated goal of this exercise is to understand the extent and impact of such regulatory practices on prices, revenues, innovation, and consumers, both within member countries and across the OECD.

BIAC would be happy to participate in this information-gathering exercise, provided that we can also participate in establishing the framework and scope of the analysis.

This first stage of the OECD project should include:

- Selection of a sufficient sample of OECD countries to be examined, including countries with policies favouring research and development
- Study of interdependencies in the pricing schemes and their impact on market access delays across the OECD
- Description of health care systems
- Description of the official purposes and legal basis of the existing price regulations
- Examination of the pricing environment for new on-patent products, as distinct from branded off-patent and generic products. OTC product regulation should also be examined.
- Analysis of the impact of reimbursement practices on pricing
- Analysis of differences between outpatient and hospital practices
- Classification of pricing regulation in terms of their impact on competitive conditions for:
 - New products
 - New versus older products
 - generics

- Classification of pricing policies in terms of their impact on intellectual property protection and market access delays
- Analysis of the success of special incentives schemes, such as for orphan drugs or for paediatric products
- Impact of pharmaceutical price regulation on overall health care costs

The second stage of the project would need to focus on generating the data necessary to measure these effects quantitatively. The Pharmaceutical Pricing Policy and Innovation project can potentially contribute significantly to the OECD's work on economic growth in general, and possible future work on health-related innovation in particular. The approach outlined above requires a large amount of data and resources. Consequently, it behoves DELSA to draw upon past, ongoing, and upcoming OECD projects on similar topics, and to assure close cooperation within the organisation and with external partners including BIAC.

Annex

Studies on Pharmaceutical Innovation/Competitiveness and the Value of Innovative Medicines – For OECD Pharmaceutical Pricing Project

The R&D Gap

Gilbert and Rosenberg, “There’s No Such Thing as a Free Drug,” Bain & Company (4/19/2004)

- Documents the widening gap in pharmaceutical R&D investment between US and Europe.

Competitiveness and Industrial Policy

EFPIA, “Pricing and Reimbursement Issues: Overview of Cost-Containment Plans – 2005 Update” (February 2005)

- Updates the main cost-containment measures affecting pricing, reimbursement and prescribing of medicines that have been implemented by European governments since 2003; estimates the direct impact of cost-containment measures on industry.

Pammolli, Riccaboni, and Magazzini, “European Competitiveness in Pharmaceuticals” (2005)

- Concludes that the US lead over Europe has accelerated, but also notes that pressure on the US model is increasing as a result of growing global dependence on US-generated R&D.

Charles River Associates, “Innovation in the Pharmaceutical Sector: Study Undertaken for the European Commission” (2004)

- Reviews evidence on the level and drivers of pharmaceutical innovation
- Finds that historic volatility is a cause of the current approval lag, and that policy makers need to promote faster market access and streamlining of the regulatory process

Pammolli, F., and Riccaboni, M., “Market Structure And Drug Innovation,” *Health Affairs*, January/February 2004; 23(1): 48-50.

- Analyzes the impact of the interplay between technological advances in pharmaceutical R&D and increased pharmaceutical cost-containment on the future dynamics of the pharmaceutical industry.
- Finds that expanded reference pricing and similar cost-containment measures could inhibit competition and enhance concentration in the pharmaceutical sector. Increased regulation would shrink the market and reduce anticipated profits, thereby undermining continued pharmaceutical innovation.

The European Commission, “A call for action to strengthen the European-based pharmaceutical industry for the benefit of the patient” (2003)

- Examines the competitiveness of the European pharmaceutical industry
- Finds that the pharmaceutical industry generates wealth and employment, that Europe is lagging being the US in pharmaceutical innovation, and that regulation should be streamlined and the science base strengthened.

The European Commission: “Life Sciences and Biotechnology: A Strategic Vision” (2001)

- Reviews the state of the biotech sector in Europe against trends in the US

- Recommends additional public sector support for biotech start ups and changes in the regulatory environment to ensure that the sector attains the critical mass to compete globally

Jacobzone, S., "Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals," OECD DELSA Occasional Paper No. 40 (April 2000)

- Describes recent trends in pharmaceutical expenditure and financing; discusses the economics of pharmaceutical markets; and reviews national policies and their attempts to balance public and private objectives.
- Argues that reform of national pharmaceutical pricing policies must foster efficiency while preserving equity, especially through greater market pressure to obtain competitive prices for non-patented drugs while allowing higher prices for patented medicines
- Warns that incentives for innovation will be diminished if prices of innovative medicines are set too low, and recommends that the costs of R&D be shared at the international level.

Gambardella, A., Orsenigo, L. and Pammolli, F., "Global Competitiveness in Pharmaceuticals: A European Perspective: A report prepared for the European Commission" (2000)

- Compares Europe's pharmaceutical competitiveness to that of the US
- Finds that the industry is important for health outcomes and the economy, but that Europe's research-based pharmaceutical industry is lagging due to regulation and a poor research environment.

UK Pharmaceutical Industry Competitiveness Task Force (March 2001)

- Report on a broad consultation process focusing on supply, demand and regulatory conditions affecting UK industry – a model for industry-government relations now emulated elsewhere in the EU.
- Finds that the industry's contribution to the UK economy is strong but foreign investment is weakening and take-up of new medicines slow compared to US and other EU countries
- Annual reporting on 46 performance indicators – most recent in autumn 2004

The Benefits of New Innovation

Lichtenberg, F.R., "Benefits and Costs of Newer Drugs: An Update," NBER Working Paper 8996 (2002)

- Quantitative analysis of the link between drug age and medical spend.
- Finds that using newer drugs reduces non-pharmaceutical spending 7.2 times more than it increases pharmaceutical spending

Lichtenberg, F.R., "Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS," *Health Affairs* 20(5): 241-51(2001)

- Examines data from the 1996 Medical Expenditure Survey.
- Finds that those consuming newer drugs had fewer hospital stays, lower non-drug spending, lower mortality, and fewer days of lost work

Cutler, D.M. and McClellan, M., "Is Technological Change in Medicine Worth It?" *Health Affairs*, Vol. 20, No. 5, pp. 11-29 (2001)

- Analysis of costs and benefits of pharmaceutical innovation for 5 conditions.
- Finds that pharmaceutical technology often leads to more spending, but the benefits derived outweigh the costs

Lichtenberg, F.R., "Do (More and Better) Drugs Keep People Out of Hospitals?" *American Economic Review* 86: 384-8 (1996)

- Quantitative analysis of disease-level data between 1980 and 1991.
- Finds that higher pharmaceutical use reduces hospital bed days. A \$1 increase in pharmaceutical spending is associated with a \$3.65 reduction in hospital spending (though ambulatory spend rises by \$1.54)

NERA/ABPI, Human and Economic Value of Pharmaceutical Innovation and Opportunities for the NHS (May 2004)

- Examines future health and economic costs in the UK created by two diseases – diabetes and CHD – and how more use of innovative medicines would affect these costs.
- Finds that use of key medications for diabetes would save the NHS 380,000 hospital bed days by 2007. Use of statins would save 120,000 bed days per year by 2007, for savings of 218 million sterling

The Relationship Between Health and Wealth

Nordhaus, W.D., “The Health of Nations: The Contributions of Improved Health to Living Standards,” Ch.2 in *Measuring the Gains from Medical Research*, Murphy, K.M. and Topel, R.H., (2003)

- Analysis of a measure of national income that includes health gain.
- Finds that the social productivity of health care spending may be substantially higher than any other type of spending

Murphy, K.M. and Topel, R.H., “The Economic Value of Medical Research,” Ch.3 in *Measuring the Gains From Medical Research*, Murphy, K.M. and Topel, R.H., (2003)

- Develops an economic framework to estimate the value of changes in life expectancy.
- Finds that spending on medical research is becoming more valuable and current spending is small relative to the economic value of past improvements in health. Medical advances that produce 10% falls in mortality from cancer and heart disease would add \$10 trillion to national wealth

Lichtenberg, F.R., “Pharmaceutical Innovation, Mortality Reduction, and Economic Growth,” Ch.4 in *Measuring the Gains From Medical Research*, Murphy, K.M and Topel, R.H., (2003)

- Provides a model of the relationship between new-drug use and mortality.
- Finds that the social rate of return to pharmaceutical innovation based on mortality impacts is around 70% (including quality of life impacts would increase this).

Bloom, Canning and Sevilla, “The Effect of Health on Economic Growth: Theory and Evidence,” NBER Working Paper Series, No. 8587 (2001)

- Analysis of production function models to take account of health and work influences.
- Finds that each added year of average life-span adds around 4% to national output

Bloom and Canning (2000) “The Health and Wealth of Nations,” *Science*, Vol. 287, 1207-1208 (2000)

- Analysis of trends in life expectancy and economic growth.
- Finds that better health can increase wealth through productivity improvement, increased education and investment in physical capital. An increase in life expectancy of five years would increase economic growth by 0.3-0.5% per year.

Bioscience Innovation and Growth Team, “Bioscience 15: Improving National Health, Increasing National Wealth” (2003)

- Considers challenges facing the bioscience sector in the UK.
- Produces a number of recommendations to aid the industry. States that improved clinical performance and access to innovative medicines improves health, while national wealth is increased due to maintaining a high-growth industry

Patient Access to New Medicines

Ridley, D., "Price Differentiation and Transparency in the Global Pharmaceutical Marketplace," *Pharmacoeconomics* 2005: 23 (7), pp. 651-658.

- Analysis of the welfare effects of differential pricing, the optimal role for international health organizations in promoting access to medicines, and the impact of greater price transparency (e.g., through reference pricing and international price comparisons) on the ability to price-discriminate and expand access to innovative medicines for both wealthier and poorer consumers.
- Finds that WHO efforts to increase transparency are likely to inhibit price differentiation and restrict access to innovative pharmaceuticals; urges international organizations to promote continued innovation and expand access to medicines by dissuading governments from making price comparisons and basing their prices on those of lower-income countries.

Danzon, P.M., Wang, R. and Wang, L., "The Impact of Price Regulation on the Launch Delay of New Drugs – Evidence From Twenty-five Major Markets in the 1990s," NBER Working Paper 9874 (2003)

- Analysis of country characteristics on launch of NCEs (UK and US, 1994 and 1998)
- Finds that the probability of launch is positively affected by price and income, and negatively affected by regulation. The cost of delayed access is unlikely to be outweighed by the benefits of higher use due to lower prices

Schoffski, O., "Diffusion of Medicines in Europe: Report Prepared for the European Federation of Pharmaceutical Industries and Associations" (EFPIA, 2002)

- Analysis of the diffusion of the most effective drugs for 20 diseases
- Policy factors (e.g., pricing policies) are the key drivers of the diffusion of innovation. Medical treatment in Europe is sub-optimal, with low (and varied) levels of new drug diffusion

Cambridge Pharma Consultancy, "Delays to Market Access in Europe" (2002)

- Assessment of delays in access to new medicines (1997-2001)
- Many countries exceed time limits specified by the EU for P&R decisions, often by over 100%. Reimbursement decision delays tend to be longer than pricing decision delays

Charles River Associates, "Global Pricing Strategies for Pharmaceutical Product Launches," Chapter 2 of the *Pharmaceutical Pricing Compendium* (2003)

Impact of Price Controls

Bain & Company, "Addressing the Innovation Divide," *In Vivo, The Business and Medicine Report*, Vol. 22, No. 3 (2004)

- Analysis of US-Europe relationship regarding pharmaceuticals
- Finds that Europe's free-ride on US R&D is costly (in terms of delayed access to medicines, poorer health outcomes, and lower investment in R&D). Europe losing out to the US, and the situation will be exacerbated unless innovative drugs are rewarded appropriately in Europe

Boston Consulting Group, "Adverse Consequences of OECD Government Interventions in Pharmaceutical Markets on the U.S. Economy and Consumer" (2004)

- Modeling of volume and price data in 8 countries, plus review of literature and macroeconomic data

- Finds that if OECD governments did not control pharmaceutical prices, an additional \$17-22bn would have been spent on R&D in 2003, resulting in a 50% increase in NCEs

US Department of Commerce, "Pharmaceutical Price Controls in OECD Countries: Implications for US Consumers, Pricing, Research and Development and Innovation" (2004)

- Uses multipliers to estimate the scale of R&D in the absence of price controls
- Finds that price controls in OECD countries have reduced pharmaceutical revenue by \$18-27bn, which has reduced R&D by \$5-8bn per year (equivalent to 3 to 4 NCEs)

Vernon, A., "Examining the Link Between Price Regulation, Re-importation, and Pharmaceutical R&D Investment," AEI Brookings Joint Centre for Regulatory Studies (2004)

- Analysis of financial data of the largest 30 pharmaceutical companies
- Finds that regulation of prices in the US could lead to a decline in R&D intensity of between 23 and 33 per cent

Danzon, P.M. and Furukawa, M.F., "Prices and Availability of Pharmaceuticals: Evidence From Nine Countries" (2003)

- Analysis of price differentials in a number of countries
- Finds that price differentials are correlated with income differentials. Mark-ups over marginal cost are efficient and equitable to cover R&D costs. The US industry structure is more helpful to R&D

Santerre, R.E. and Vernon, J.A., "Assessing Consumer Gains From a Drug Price Control Policy in the U.S.," NBER Working Paper 11139 (2005)

- Uses US national data from 1960 to 2000 to estimate private consumer demand for pharmaceuticals and examines the impact of holding down drug prices.
- Finds that the benefits of lower prices to consumers were less than the benefits to society of new drugs forgone (because lower prices imply less scope for R&D and hence fewer NCEs discovered)

Abbott, T.A. and Vernon, J.A. , "The Cost of US Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions," NBER Working Paper 11114 (2005)

- Uses a prospective micro-simulation approach to model how future price controls in the US will effect early-stage R&D decisions
- Finds that price controls would significantly decrease the amount of R&D undertaken in the U.S. – reducing prices by 40-50 per cent would lead to 30-60 per cent less early-stage R&D projects being undertaken