



The Voice of OECD Business

BIAC Talking Points

OECD High-Level Symposium on Pharmaceutical Pricing Policy

27 October 2008

Introduction

In December 2005, BIAC submitted a paper summarizing its views on the initial discussions on the OECD project on pharmaceutical pricing. BIAC members, who represent employers and business, including pharmaceutical and biotechnology companies, understand and empathize 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.

Employers have to struggle with continually increasing health care costs. Health care systems are facing major challenges, which are being exacerbated by the financial crisis. The crisis is likely to have major implications for patients, industry, productivity and resources available for innovation. Considering the challenges our health care systems are facing, reforms are necessary. 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 labor cost and compulsory health insurance contributions on employment, consumption, competitiveness and overall economic growth. 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.

General points to be mentioned throughout the meeting where appropriate

I. Refer to the economic crisis and implications for innovation

Health care systems are facing considerable challenges; which are being exacerbated by the financial crisis. The crisis is likely to have major implications for patients, industry, productivity and resources available for innovation. We need to take the current situation into consideration and look for ways of how to address the consequences it could have for innovation. The implications of the current economic situation and ways of how the consequences could be addressed should be given due considerations throughout the discussions at this meeting.

II. Underline the positive aspects of the OECD report

While BIAC does not agree with all parts of the analysis and has several concerns, there are also a number of positive points in the OECD report, which we would like to highlight. The OECD report typically employs sophisticated reasoning on numerous issues that are usually subjected to far less rigorous examination, and the report often takes care to present two sides of many topics that are usually discussed in a less even-handed manner. Furthermore, it makes a valuable contribution in bringing together research literature from many disparate sources. Some specific examples include the following:

- **Profits:** The brief discussion of industry profits is far more even-handed than most discussions. It correctly notes that if one corrects for accounting methods, profits are not extraordinarily high compared to other leading industries. A later discussion provides a valuable update on the historically close empirical relationship between industry sales and R&D expenditures.
- **Drug approvals and registrations:** The report acknowledges that delays in authorization significantly retard the availability of new drugs and in particular, several OECD nations have been slow to adopt new breakthrough drugs.
- **Monopoly and monopsony of market power.** The report contains a deep discussion of market power which emphasizes that monopsony power by buyers (usually national health systems) can be as important as monopoly powers by sellers. The discussion recognizes that a single-payer system is quite different from a government subsidized system in which there are some elements of competition among buyers.
- **Price controls generally:** The extended discussion of price controls describes the complexity and opaqueness of price regulation. It claims that regulation often extends beyond patented drug prices to include generic drug price and entry, and to exert control over distribution including pharmacy markups, thus increasing drug costs unnecessarily and even adversely affecting public health.

Session-specific talking points

Session 1

Session description: *“Access and affordability of medicines in OECD countries will be the topic of discussion in the first session. Participants will discuss the challenges associated with ensuring this objective, including emerging challenges relating to very high-cost specialty medicines, and the role of pharmaceutical policies in facilitating or impeding this objective. The experience with innovative policies designed to maximize access for a given budget constraint, such as price-volume agreements, will be examined.”*

Talking points:

- BIAAC understands the challenges associated with ensuring access to medicines while managing affordability in OECD countries, and we applaud the OECD’s efforts to address this topic.
- In working to achieve this objective, we urge the OECD to be mindful of the following imperative considerations:
 - While it is tempting to think of innovative medicines in terms of immediate cost to pharmaceutical budget, it is at the same time essential to consider the benefits they bring to patients, the cost-savings they provide to other budget areas including overall healthcare (e.g., fewer hospital days, fewer surgeries) and the social system (e.g., lesser need for disability, more productive work force) as well as the positive effects of a healthy workforce for economic growth. Efficiency improvements in the health sector should address the range of options that are available.
 - Furthermore, innovation must not be limited in definition to scientific break-throughs, but should recognize incremental improvements as well. Like most other industrial sectors, innovation in the pharmaceutical industry takes place through evolutionary steps which yield improvements in efficacy, tolerability, and new uses over time which fuel incentives for further development to continue improving. For patients and physicians, these incremental and differential improvements have value as well; different patients respond differently to even slightly different medicines within the same class. When access to incrementally different medicines within a class is restricted, patients are treated with a one-size-fits all approach to medicine.

Session 2

Session 2 description: *The second session will focus on the twin goals of promoting valued innovation and obtaining good value for money in pharmaceutical expenditures. Are these objectives in conflict, requiring a tradeoff? Or can certain policies be used to achieve both goals simultaneously? Discussants will consider the evidence as to whether OECD countries are getting the best possible value for the money they spend on pharmaceuticals, and what is the scope for aligning the incentives for innovation in accordance with health improvement priorities.*

Talking points:

- BIAC appreciates the recognition by the OECD of the importance of innovation in its final report. An overall favorable policy environment for innovation as well as efficient management of the available resources is essential.
- While it is tempting to think of the pharmaceutical expenditures as the key problem, attention to other areas can help alleviate this pressure. For instance, distribution systems can be made to operate more efficiently, appropriate use of generics can help free-up resources, and prevention programs can reduce need for medication. Careful consideration should be given to overall health care budget and efficiency improvements in all areas.
- While the report suggests comparative effectiveness and health technology assessment (HTA) may be a critical ingredient in balancing static and dynamic efficiency, it does not sufficiently discuss the methodological challenges of conducting these assessments, which are the subject of ongoing international discussion. Assessment structures must not only consider cost benefits of a medicine but benefits to society as well. If cost-constrained OECD nations continue to expand assessment systems favoring cost benefits without appropriately incorporating societal benefits, static efficiency will further blunt the trend toward dynamic efficiency (*give examples*).
- Policies intended to create good value must be designed so that they do not focus on short-term cost containment at the expense of society's long-term needs (*give examples*).

Session 3

Session 3 description: *The third session will look at the ways in which pricing policies and commercial practices interact with one another in an increasingly interconnected global market. The session will explore how the threat of parallel or cross-border trade and the widespread practice of using external benchmarks to cap prices for innovative products influence manufacturers global launch and pricing strategies, and the timely availability and prices of new products in OECD countries. It will also consider how the use of confidential rebates and so-called clawbacks (which result in an effective price that is lower than the public list price), as well as the strategic launch sequences used by manufacturers (which favor high-price countries for early launch), raise questions about the reliance on external benchmarking in pricing policy. Discussion will centre on the question of what constitutes a rational framework or principles for pricing policy in an increasingly global market. On what grounds should pharmaceutical prices be expected to vary across and within countries? Is transparency in both pricing policies and prices desirable and feasible?*

Talking points:

- BIAC understands the desire to explore ways in which pricing policies and commercial practices interact in an increasingly global market and we applaud the OECD's efforts to explore this area.
- In the context of this session as well as other OECD work products from the Health Committee, pharmaceutical companies are conveyed as price makers rather than price takers. We urge you to reconsider whether this is in fact truly accurate.
 - In fact, in most OECD markets government agencies have tremendous power through strict regulations. Pharmaceutical companies are subject to mandatory price reductions, limited patent protections, increasingly onerous clinical and regulatory hurdles, and so on.
 - The nature of new drug development is highly unpredictable—2 in 10,000 molecules will ever reach market and 3 in 10 products that do will ever recoup R&D costs. As such, to continue absorbing risks associated with innovation, pharmaceutical companies must be appropriately incentivized. It should be underscored that this reward can come in different forms including price, broad access to appropriate patient population, recognition in therapeutic guidelines, and speed of access.
 - As the OECD considers principles for cost containment in an increasingly global market, the direct impact of these policies on R&D must be kept in mind. The OECD's report on pricing policy did not directly address this relationship, however there is a considerable amount of growing research we would welcome the opportunity to share.