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BIAC Contribution for the OECD Workshop on 24 June 2015

"High Cost Medicines: Are New Pharmaceutical Business Models Compatible with Efficient and Sustainable Public Spending in Medicines?"

Executive Summary

BIAC welcomes the opportunity to share perspectives in advance of the OECD workshop, "High Cost Medicines: Are New Pharmaceutical Business Models Compatible with Efficient and Sustainable Public Spending in Medicines?" BIAC represents a range of industry sectors, including the innovative biopharmaceutical sector, which is committed to the research and development (R&D) of new treatments and cures for patients, including those who have serious unmet medical needs. Innovative biopharmaceutical companies have invested more than $550 billion in R&D since 2000[i].

BIAC applauds the OECD's goal of encouraging policy dialogue between governments, experts, and industry stakeholders on important issues of health systems sustainability and access to medicines. Our **members recognize the challenges that OECD countries face in expanding access to healthcare while** managing constrained budgets. To improve access to medicines and to healthcare more broadly, and to achieve better efficiency, we believe collaborative multi-sectoral approaches are needed to advance sustainable policy solutions to healthcare financing, delivery, infrastructure, and human resources challenges, among others.

Industry is committed to engaging constructively and in a consultative manner with the OECD on important topics related to the biopharmaceutical business model, innovation, and government pricing and reimbursement of medicines. Accordingly, consistent with the workshop's themes we believe it is important that any discussion on efforts to create health systems efficiencies should recognize the following six core principles.

1. **Innovative Medicines Improve Patient Lives:** For many patients and their families, research in medicines from the innovative biopharmaceutical sector represent the only chance for survival. These medicines and vaccines offer in addition to other health technologies hope and enable patients to live longer, healthier, and more productive lives.
2. **Assessing Value of Medicines Requires a Holistic Approach:** A holistic approach to the assessment of value of medicines that recognizes patient benefits and health systems efficiencies is needed.
3. **Innovation Requires Investment in Health:** The research and development process in medicines is long, costly, and complex, however, innovative medicines pave the way for cost saving generics and create "headroom for innovation" so countries can create further health system efficiencies.
4. **Innovation Can Deliver Significant Patient and Societal Value:** Medicines development is strongly targeted at societal disease priorities and medicines are highly scrutinized to prove value before entering the market.
5. **A "Whole Health System" Approach is Needed to Maximize Efficiencies:** Efforts to create health system efficiencies should consider all aspects of healthcare, not solely focus on pharmaceutical expenditures.

6. **Multi-sectoral Partnerships Can Help Address Access and Affordability:** The innovative biopharmaceutical sector in additional to other health technology sector supports government policies that foster the use of innovative approaches to address patients' ability to pay for medicines. Together, governments, industry, patients, and other stakeholders can work together to enhance patient access to medicines.

BIAC Detailed Perspectives

Building off of the six core policy principles above, BIAC would like to share the following perspectives:

1. Innovative Medicines Improve Patient Lives: Patients are living longer, healthier, and more productive lives thanks to innovative medicines and vaccines developed by research-based biopharmaceutical companies.

- For many patients and their families, research and medicines from the biopharmaceutical sector represent the only chance for survival.
- A short time ago, HIV/AIDS was considered a death sentence. By 2012, the U.S. death rate for HIV/AIDS had dropped nearly 85 percent. Today, it is considered a manageable disease.[ii]
- Since its peak in 1991, the cancer death rate in the U.S. has fallen 20 percent and 2 out of 3 patients diagnosed with cancer are living at least 5 years following diagnosis.[iii]
- New hepatitis C therapies have cure rates above 90 percent and dramatically decrease the burden of the disease on OECD health systems and economies.[iv, v]
- According to the WHO, no other public health intervention except the provision of clean drinking water has done more to reduce the global burden of infectious disease than vaccines.[vi]

2. Assessing Value of Medicines Requires a Holistic Approach: A holistic approach to the assessment of value is needed. Focusing exclusively on the cost of medicines in isolation ignores direct benefits to patients, significant efficiency and cost savings elsewhere in health and social systems as well as the wider economy.

- The development of new medicines is essential to shifting the treatment paradigm towards cure and prevention, helping patients avoid expensive hospital visits, long-term care and social expenditure, whilst supporting economic growth concomitantly. By supporting and encouraging innovation, OECD countries can address cost challenges their health care systems face.
- A recent study in the U.S. found that without efforts to address Alzheimer's, the annual costs to all payers for caring for patients with the disease is expected to increase to more than $1.1 trillion in 2050.[vii]
- Another recent study found that every additional dollar spent on medicines for adherent patients with congestive heart failure, hypertension, diabetes, and high cholesterol generated $3-$10 in savings on emergency room visits and inpatient hospitalizations.[viii]
- Ill-health is a major cause of productivity loss and early labor market exit, with many causes being addressable. For example, around two thirds of the health-related lost economic output are due to mental health and cardiovascular diseases.[1]

[1] Source: European Commission: Health of People of Working Age(2011); European Commission: Health Systems and Health care in the EU (2012)

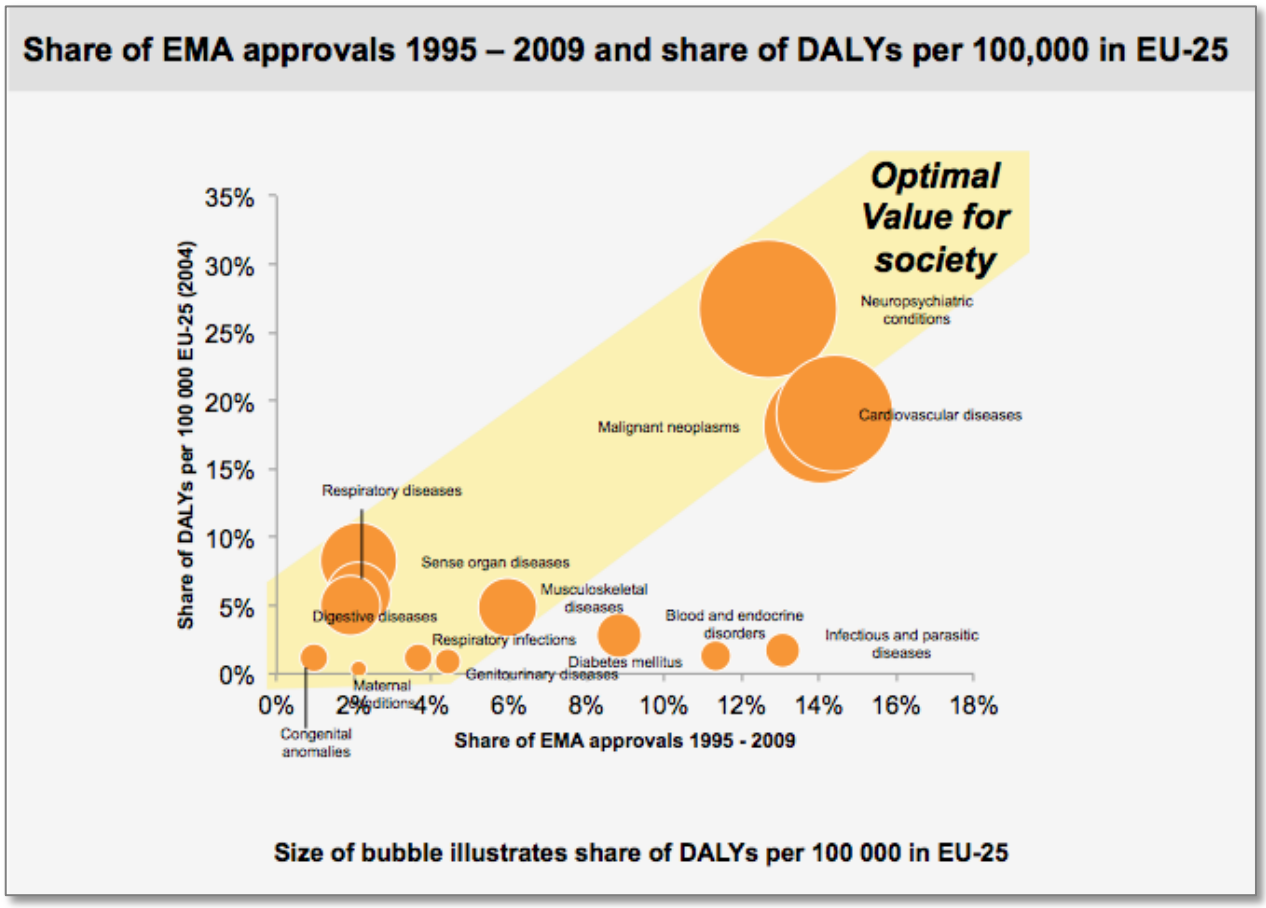
3. Innovation Requires Investment in Health: Innovative medicines offer great hope to patients, but developing these new treatments and cures is a long, costly, and complex process, and biopharmaceutical companies face growing challenges in research and development of new treatments for patients.

- On average it takes 10 years and $2.6 billion to research and develop a new medicine, including the cost of failures.[ix]
- Importantly, investments made by innovative biopharmaceutical companies pave the way for generics. In the EU for example, average prices (on a volume weighted basis) have declined over the last decade, driven by generic penetration and utilization. In the U.S., spending on prescription medicines has remained a relatively constant share of total spending due to the high rate of generic utilization (more than 4 out of 5 prescriptions are now filled with generic medicines) and competition among brand-name medicines.
- These efficiencies help keep medicines bills in check via headroom for innovation since the reduction in cost of previously patented medicines releases resources that can be used for new medicines.
- Today, more than 7,000 medicines are in development around the world.[x] 70 percent of these treatments are potential first-in-class therapies.[xi]
- Since 2000, biopharmaceutical companies have invested more than $550 billion in the search for new treatments and cures, including an estimated $51 billion in 2013 alone.[xii]
- Many companies utilize innovative pricing models to enhance access to medicines for patients globally. Working together, governments and the pharmaceutical industry have a role to play in ensuring access to medicines and delivery of high quality, effective health interventions. In developed countries with more established health infrastructure and delivery systems, governments should invest in healthcare including pharmaceuticals at a level commensurate with countries of similar levels of development. Where countries set prices of medicines with reference to prices in countries of dissimilar health, economic, or epidemiological status, such mechanisms pose potential risks of product shortages, parallel trade, and disruption in patient access.

4. Innovation Can Deliver Significant Patient and Societal Value: Medicines development is strongly targeted at societal disease priorities and medicines are highly scrutinized to prove value before entering the market.

- Industry pipelines have historically been targeting major unmet medical needs and there is a strong association between current industry pipelines and priority disease areas. For example analysis published by EFPIA shows that pipeline projects are broadly correlated with the disease areas that are associated with the most disability life years (DALYS), see figure 1.

Figure 1



Source: Catala-Lopez, F. et al: Development of new medicinal products in the European Union (2010); A.T. Kearney analysis Found in EFPIA Health and Growth Evidence Compendium http://www.efpia.eu/documents/110/138/Health-amp-Growth-Evidence-Compendium

- Many new areas of innovation offer extremely high patient and societal value including treatments for hepatitis C, oncology, and diabetes.
- The value of medicines is more closely scrutinized than any other area of public expenditure across the OECD.
- Pharmaceutical companies increasingly invest substantial resources not only in data to support regulatory processes but in real world data, often throughout the life cycle of a medicine, to support decision making by health systems. Early discussions with payers and HTA agencies during development of a new drug help ensure the data generated is as useful as possible to all stakeholders.
- Methods and processes used to assess the value of medicines vary greatly throughout the OECD and there is no 'one perfect model' – each has to fit with the specific characteristics of the system it is intended to serve. All such methods and processes need to be continually improved and reformed to ensure they are keeping pace with scientific developments and are fit for purpose – for instance as personalized medicines allow a more targeted approach to treatment it will increasingly be inappropriate to base decisions on population averages.
- The pharmaceutical industry is actively engaged with regulators, payers and other stakeholders to help ensure value assessment is as appropriate as possible.
- Many pharmaceutical companies are engaged in innovative, product-specific arrangements with payers on schemes that help manage the introduction of a product

within a system (managed entry agreements), that share risk, or that tie payment or pricing to the real world performance of the product.

- Medicines should be evaluated based on the benefits they provide to individual patients and the potential to extend and improve the quality of their lives. Average survival rates are important, but do not account for the many patients that will survive much longer.
- Medicines often demonstrate far greater benefits to patients than understood at the time of initial approval. During the clinical trial process, potential medicines are studied in specific patient populations, often those with the most advanced form of the disease. However, after a new medicine is approved it may have a greater impact for patients earlier in the progression of their disease or in combination with other therapies.

5. A "Whole Health System" Approach is Needed to Maximize Efficiencies: Efforts to create health system efficiencies should take into account maximizing quality patient outcomes and should consider all aspects of health care expenditures.

- We applaud the efforts of the OECD to explore how health systems can improve efficiency of resource use and, thereby, help ensure the financial sustainability of health care systems.
- While we understand that medicines are the most scrutinized part of public health budgets as governments cope with high budget impacts, we urge policymakers to look at biopharmaceutical expenditures compared with other health expenditures and its contribution in avoiding social cost or improving productivity.
- There is an increasing body of evidence from the most advanced health systems in the world that healthcare reform that focuses on health outcomes can both improve the quality of care and reduce cost. Specifically, international efforts by disease area to identify meaningful outcomes' metrics will allow for both an increase in transparency about what works, as well as an opportunity to study the causes of practice variation. Such insights can help design more effective treatment pathways. Reform in support of outcomes-based systems, should remove budget silos and allow those managing care to optimize all inputs, including medicines.
- According to OECD data, pharmaceutical expenditures account for a relatively minor share of total health expenditure in most OECD countries; furthermore growth rates are generally slower for pharmaceuticals than those of other health expenditures, many of which are increasing rapidly.
- Currently, overall medicines across Europe represent less than 15% of total expenditure although variations exist between therapy areas.[xiii]

6. Multi-sectoral Partnerships Can Help Address Access and Affordability: Addressing access and affordability requires good planning, an integrated approach to budgets, and a multi-sectoral partnership approach.

- The capacity of the innovative biopharmaceutical industry to ensure access to medicines relies upon joint industry and government commitment and partnership to address healthcare challenges, be it national, regional or global.
- We have recently seen 'affordability' challenges for medicines which have proven value for the system overall. In practice the affordability challenge has often been at the local budget holder level – particularly in decentralized health systems - as opposed to the system as a whole. This has been the result of poor planning and/or poor information about both the cost and system implications of the new medicine. A better dialogue between industry and health systems about industry pipelines, and the implications of products about overall cost, as well as about care pathway design, could help health

systems manage the introduction of new technologies whilst at the same time improve outcomes for patients.

- The innovative biopharmaceutical sector supports government policies that foster the use of innovative approaches to address patients' ability to pay for medicines.
- Tiered pricing (also known as differential, preferential, or flexible pricing) in which manufacturers have the practical flexibility to price their medicines differently for different segments of a market to improve patient access to medicines, is, among others, one potential approach for enabling sustained access to high quality affordable innovative medicines to patients all around the world who currently lack such access, while preserving incentives for innovation.
- Many biopharmaceutical companies are also engaged in patient assistance programs to provide access to medicines for patients in need. See IFPMA's Health Partnerships Directory for a comprehensive list of examples at: http://partnerships.ifpma.org/partnership/patient-access-program

Innovative medicines developed by biopharmaceutical companies have been transforming patient care for over a century – enabling patients to live longer, healthier, and more productive lives, and helping to create more sustainable health care systems as well as supporting economic growth and competitiveness. Investing in health should be a priority for OECD countries. BIAC stands ready to engage with the OECD Health Committee to share our perspectives to enhance access for patients, ensure health system sustainability and contribute to economic growth and competitiveness of its member countries.

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[xiii] OECD Health Statistics Database (accessed 2013); A.T. Kearney analysis (2012); Schwarzkop et al. (2010); Damm et al. (2012).