Biotechnology Industry Organization

May 5, 2013

Mr. Raj Kumar
Undersecretary
Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Shastri Bhavan
New Delhi INDIA

Via Electronic Mail: uspi3-pharma@nic.in

Dear Mr. Kumar:

Thank you for the opportunity to comment on the Department of Pharmaceuticals' "Report of the Committee on Price Negotiation of Patented Drugs". By way of introduction, the Biotechnology Industry Organization (BIO) is an industry association based in the United States that represents over 1,100 biotechnology companies, scientists and research institutions from around the world. It is our mission to be the champion of biotechnology and the advocate for its member organizations - both large and small. Our members - many of whom are small emerging companies - are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. Our members work every day to improve the human condition by curing the sick, feeding the hungry or developing cleaner, safer and healthier sources of energy. We understand the challenges that India faces with respect to healthcare and the innovative biotechnology industry stands ready to work with India to help address them.

Thank you again and we look forward to working with you in the future as India implements its vision for an innovation-based biotechnology industry.

Sincerely,

Lila Feisee
Vice President, International Affairs

Enclosure

Comments of the Biotechnology Industry Organization (BIO) on

The "Report of the Committee on Price Negotiation for Patented Drugs"

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. The majority of these companies are small and medium-sized biotechnology companies, developing their first products. Biotechnology research and development requires substantial investment of time and financial resources, and is laden with risk of failure. Not surprisingly, the ability to recoup their investment is a vital concern of these companies. If this ability is constrained by government policies, they will naturally shift their scientific efforts elsewhere. This holds true whether the inventor is based in India or in the United States.

Nonetheless, BIO's members recognize the needs of Indian patients who have limited or no access to health and medicines in particular. We applaud the efforts of the Central Government, as well as some states, to purchase and provide at low-cost or no-cost essential medicines to its citizens with limited means. Moreover, BIO recognizes that innovation in the biotechnology sector may hold the answer to many of India's challenges. Thus, it is important for the Government of India to develop policies that address the needs of Indian patients without hindering the ability of innovative companies to develop and produce the medicines that patients around the world need. In doing so, it is essential that the costs and benefits of such proposed policies be carefully assessed. We respectfully submit the comments below with this perspective in mind.

General Comments:

- BIO notes that India is systematically implementing price controls on various aspects of the pharmaceutical market including medicines on the essential drug list. As a general rule, BIO opposes price controls as a means for reducing the cost of medicines because of the detrimental impact such policies have on innovation. However, regardless of the

nature of such policies, if they are implemented, they should be limited only to such medicines that are purchased by the government.

- The key to the success of the biotechnology industry – across all of its sectors – is a business model that is based on taking significant risks to develop products based on innovation. Specifically, the biotechnology business model is based on making significant investments (often hundreds of millions of dollars) in research and development with the hope that some of these investments and efforts will yield a commercial product. This model has worked despite the fact that it is lengthy (often taking more than a decade) and that most biotechnology R&D investments and efforts do not result in a commercial product ever reaching the market. It is only by pushing the boundaries of science and taking these risks that breakthrough inventions are discovered and converted into commercially viable products and services.

- Given these significant R&D risks, the biotechnology business model requires an environment that, as much as possible, eliminates unpredictability and allows for recoupment of the value of the successfully approved products. Among the factors necessary to spur innovation in this sector is the ability to recoup the investment made in the R&D endeavor. Specifically, by ensuring that the products or services that may eventually be marketed are successfully commercialized, companies can justify taking risks and making significant R&D investments. Government price controls are often unintentionally arbitrary and do not capture the true value of the product and hence limit the success of commercialization. Such mechanisms will adversely affect the investment and the business environment that is so crucial to supporting innovation in the biotechnology sector.

- With respect to patented medicines, BIO notes that in India, such medicines currently represent a very small fraction (0.04% of the market turnover) of the Indian pharmaceutical market.[1] Controlling the price of these drugs will have little to no meaningful benefit for India's patients with respect to the cost of healthcare or access to medicines, whereas the impact on the development of new products for the Indian market can be significant. It is BIO's view that such policies will negatively impact

[1] Page 3 of the "Report of the Committee on Price Negotiation of Patented Drugs," $5 million out of a $12 billion domestic market turnover equals 0.04% of the market.

innovative companies' ability to obtain the necessary financing to develop their products.

- BIO commends the Committee for its recognition that the lack of widespread health insurance is a root cause behind the lack of access to healthcare. As the report states "The other reason is the absence of an effective health insurance system to ensure access and affordability of all medicines to all." Later on, the Committee states, "The lack of public health policy and absence of health insurance cover to majority, leading to a high out of pocket expenditure on medicines**,** have raised concerns further." BIO wholeheartedly agrees with this sentiment and suggests that as a first priority the Government continue to expand on pilot efforts to provide wide scale health insurance, particularly to its poorest citizens. However, BIO disagrees with the notion that health insurance is only for the middle class, as implied on p. 21, as all income classes can benefit from risk pooling and improved bargaining power brought about by insurance. The problem of access to healthcare goes far beyond the price of a few medicines, and to be effectively addressed must be viewed holistically.

- As Noted in p. 27 of the report even if patented medicines are distributed at no charge to patients, there will still be a large number of Indian citizens who could not afford the cost of transportation to a qualified health facility and the charges of health providers and hospitals, or the cost of generic medicines, diagnostics, laboratory tests, and medical devices that these patients would need. This further points to the need for a holistic approach to healthcare in India.

- The report correctly notes that India has become a global leader in the supply of generic medicines, primarily due to "low production costs" for Indian pharmaceutical manufacturers. However, this will not always be the case as other emerging markets continue to drive down costs through use of low-cost labor. Only by capitalizing on its scientific talent can India continue to be a leader in biopharmaceuticals. BIO urges India to take advantage of its market leadership to develop incentives for its companies to become more innovative. Policies that encourage innovation will enable India to regain and sustain its competitive edge and market share.

Specific Comments regarding the Committee's Recommendations:

- Regarding the methodology of using a ratio of per capita Gross National Income (GNI) with Purchasing Power Parity (PPP) by the Indian government to calculate the appropriate price for a medicine is a gross misapplication of this particular measure, resulting in skewed relative pricing between countries. Such a ratio is useful for comparing the relative ***incomes*** of two different countries, but is totally inappropriate for comparing the relative ***cost of goods*** between two countries. In the latter case, the appropriate factor to use is the PPP Exchange Rate. Please refer to the World Bank website for an explanation of the PPP Exchange Rate at http://data.worldbank.org/indicator/PA.NUS.PPPC.RF. This exchange rate is a far more appropriate and accurate method for comparing the costs of comparable goods between two countries. Using this methodology results in a more realistic comparison of the cost of medicines in India versus other countries.

- In regards to patented products with a therapeutic equivalent discussed on p. 31, no discussion is given to who would determine if there is a therapeutic equivalent. Such determinations should be made only by experts with significant clinical experience in the therapeutic areas in question, e.g. oncology, diabetes, cardiovascular diseases, etc. Furthermore, these determinations should consider the additional benefits of these medicines may have, such as improved dosing, decreased side effects, and other improvements leading to a higher quality of life for patients. These benefits are important to patients and should factor into the price.

- Furthermore, when considering the "cost of treatment," (p.31) the price negotiation committee should take a holistic approach to these costs, noting, for example, when use of a more expensive medicine results in lower hospitalization rates with the end result being a lower overall cost of treatment to the patient.

- For medicines developed and introduced in India first (p. 32), BIO recommends that no price negotiation or controls be placed on these medicines by the Indian government whatsoever. This is to encourage,

not discourage, the discovery of medicines primarily for the benefit of the Indian people. As noted before, placing limits on the returns of Indian biopharmaceutical companies will undoubtedly dissuade some investigators from pursuing promising discoveries.

- Regarding the composition of the Price Negotiation Committee (p. 30), BIO recommends that one or more industry representatives be added to the committee. These industry representatives should represent companies whose primary business is the development of *innovative* medicines, not generic medicines, as these innovators would have an inherently better appreciation of the costs and risks involved in developing new medicines.

- Finally, BIO also strongly recommends that in no circumstances should drug safety approval, i.e. marketing approval, be contingent on price negotiations. Patients and physicians should not be denied access to safe and effective drugs.