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GPhA Expresses Concern Trans-Pacific Partnership Agreement Negotiations Could Hinder Access and Competition to Generic Drugs

WASHINGTON, D.C. (JUNE 14, 2011) – The Generic Pharmaceutical Association (GPhA) today announced that it has sent a letter to President Barack Obama expressing concern over current negotiations on the Trans-Pacific Partnership (TPP) agreement.

Specifically, GPhA and its member companies are concerned about any effort to include provisions in the TPP agreement that would hinder competition and access to the safe and affordable medicines that the generic pharmaceutical industry provides to patients in the United States and abroad.

Provisions relating to intellectual property rights for biologic products in particular should not be included in the TPP as other stakeholders have suggested, GPhA Executive Director Bob Billings said in the letter.

GPhA believes the new pathway for the approval of biosimilars in the U.S. marketplace, which was established as part of the Patient Protection and Affordable Care Act (PPACA), can help keep pharmacy benefits affordable for patients and payors alike, thereby improving access to these lifesaving therapies.

However, while implementation of this pathway is ongoing at the Food and Drug Administration (FDA), there remains significant disagreement about how certain provisions of the new law should be implemented by the agency and whether further legislative reforms are necessary to ensure a more robust biosimilar marketplace.

“Given your administration’s position and the uncertainty surrounding the pathway’s implementation by FDA, as well as the critical need to ensure access to safe and affordable medicines in global markets, it is premature to include provisions relating to biologics in any trade agreement,” Billings said.

As the United States prepares to submit text for the intellectual property chapter related to pharmaceuticals, GPhA believes it is imperative that such provisions reflect the bipartisan New Trade Policy (NTP) of 2007, which struck a better balance between promoting innovation and ensuring access to affordable drugs.

The full text of the letter is listed below. A copy can be found at http://gphaonline.org/sites/default/files/Obama%20letter.pdf.

June 10, 2011

The Honorable Barack Obama
President
The United States of America
1600 Pennsylvania Ave., NW
Washington, D.C. 20500

Dear President Obama:

I am writing to you today regarding your administration's current negotiations on the Trans-Pacific Partnership (TPP) agreement. As you may know, the Generic Pharmaceutical Association (GPhA) represents manufacturers of approximately 90% of all generic pharmaceuticals dispensed in the United States. According to IMS Health, generic pharmaceuticals currently fill 78% of the prescriptions dispensed in the U.S., but account for only 25% of the total amount spent on prescription drugs. Through competition, generic manufacturers drive down costs and support public health by providing access to affordable medicine.

GPhA and its member companies are concerned about any effort to include provisions in the TPP agreement that would hinder access to the safe and affordable medicines that our industry provides to patients in the United States and abroad. As the United States prepares to submit text for the intellectual property chapter related to pharmaceuticals, it is imperative that such provisions reflect the bipartisan New Trade Policy (NTP) of 2007, which struck a better balance between promoting innovation and ensuring access to affordable drugs.

Further, GPhA believes that provisions relating to intellectual property rights for biologic products should not be included in the TPP as other stakeholders have suggested. Biologic medicines are a relatively new frontier in patient care and offer great promise for future treatments and therapies. Unfortunately, these therapies are often prohibitively expensive and remain out of reach for many patients. In addition, both public and private payors will face escalating health care costs as these medicines are used to treat more and more patients with chronic and complex conditions. According to recent data compiled by IMS, global spending on biologics is expected to reach as high as $200 billion by 2015.

The introduction of biosimilars to the marketplace, however, can help keep pharmacy benefits affordable for patients and payors alike, thereby improving access to these life saving therapies. That is why, as part of the Patient Protection and Affordable Care Act (PPACA), a new pathway was established for the approval of biosimilars in the U.S. marketplace. Under this pathway, innovative biologic products enjoy a lengthy 12 year period of market exclusivity, after which an FDA approved biosimilar product may enter the market. It is important to note that the 12 year exclusivity period prevents only the marketing of a biosimilar product and does not prevent the submission of applications relying on the approval of a brand product.

While implementation of this pathway is ongoing at the Food and Drug Administration, there remains significant disagreement about how certain provisions of the new law should be implemented by the agency and whether further legislative reforms are necessary to ensure a more robust biosimilar marketplace. Recognizing that the generic biologics market will be substantially different from the small molecules market, in its report on follow-on biologics[1], the Federal Trade

Commission stated that "branded biologic drugs are likely to maintain their first-mover advantages by retaining 70-90 percent of their market share years after the [follow on biologic] entry" and therefore no exclusivity period would be needed for this type of drugs. Similarly, your administration has recognized the urgent need to speed up access to biosimilar products, as reflected in your Fiscal Year 2012 (FY12) budget proposal. Specifically, under the budget you submitted to Congress earlier this year, beginning in 2012 innovator brand biologics would have seven years of exclusivity and would be prohibited from receiving additional exclusivity by "ever-greening" their products.

Given your administration's position and the uncertainty surrounding the pathway's implementation by FDA, as well as the critical need to ensure access to safe and affordable medicines in global markets, it is premature to include provisions relating to biologics in any trade agreement.

Thank you for your consideration of this important issue, as well as our other concerns pertaining to the TPP agreement which we have previously communicated to the Office of the United States Trade Representative. We look forward to working with your administration to develop an agreement that strikes the right balance between fair intellectual property right protections and ensuring access to safe and affordable medicine.

Sincerely,

Bob Billings

Executive Director

GPhA

cc:

The Honorable Ron Kirk
United State Trade Representative

GPhA represents the manufacturers and distributors of finished generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. Generic pharmaceuticals fill 78 percent of the prescriptions dispensed in the U.S. but consume just 25 percent of the total drug spending. Additional information is available at gphaonline.org.

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Generic Pharmaceutical Association - 777 Sixth Street, NW, Suite 510 - Washington, DC 20001

[1] Federal Trade Commission, “Emerging Health Care Issues: Follow-on Biologics Drug Competition”, June 2009.