Mylan Response to Brian Elliott Piece in FT Entitled, “HIV/AIDS Drugs for Developing World Face Threat of Disruption”

March 20, 2017

HERTFORDSHIRE, England and PITTSBURGH -- March 20, 2017 -- Mylan has received some inquiries from our partners regarding a false and misleading commentary published in the *Financial Times* on March 16, authored by Brian Elliott and entitled, “HIV/Aids drugs for developing world face threat of disruption.” We at Mylan were very concerned by Mr. Elliott’s piece, given its potential to cause unnecessary confusion within the HIV/AIDS community and to alarm the patients we serve. We would like to take this opportunity to address the fallacies and erroneous conclusions stated by Mr. Elliott.

First and foremost, Mylan has a long, proud history as one of the industry’s most reliable and large-scale suppliers of high-quality antiretroviral (ARV) medicines. Mylan’s facility in Nashik is not under any threat of disruption to production following an inspection several months ago by the U.S. Food and Drug Administration (FDA). Mr. Elliott’s speculation that Mylan would be unable to meet its ARV supply commitments is completely unfounded.

Mylan is one of the world’s leading generic pharmaceutical companies and has nine independent sites, including Nashik, engaged in the production and supply of ARVs to ensure multiple redundancies so that we can maintain continuous supply. Each of these sites has been subject to numerous inspections by global regulatory authorities, including the FDA. In the decade that Mylan has supplied ARVs, we have never had any supply disruption due non-compliance at any site and, again, there is no risk of supply disruption at this time. The suggestion by Mr. Elliott that Mylan facilities are at risk of halting production of ARVs and that 7 million patients might lose access to these life-saving drugs is simply untrue.

Beyond this accusation, Mr. Elliott’s commentary did not reflect an accurate analysis about the ARV market nor, in our view, did it serve the interests of the HIV/AIDS community.

First, the fact that four companies supply the bulk of ARVs in developing countries does not support Mr. Elliott’s suggestion that “the risk of supply interruption is at a worrying level.” Mr. Elliott must be aware that every brand drug is a single-source product. No one ever claimed that Lipitor® supply was at risk for nearly 20 years when it was supplied only by Pfizer. In developing countries, measles and pneumococcal vaccines, at more than 400 million doses per year, are each supplied by two manufacturers. Yet vaccine buyers don’t regard reliance on them as “dangerous,” as Mr. Elliott claimed is the case when there are no alternatives for a therapeutic condition.

Second, bulk procurement has important advantages which serve the interests of patients. The Global Fund, PEPFAR, the Clinton Health Access Initiative (CHAI) and UNITAID have adopted strategies that, in part, use consolidated volumes to achieve lower prices – by working with manufacturers to lower production costs through large scale. Low prices have allowed these organizations to reach more people who need treatment. This increased demand for ARVs, in turn, has resulted in a greater number of suppliers and competition – again, to the benefit of patients. Mr. Elliott’s commentary omitted the critical role of manufacturing scale in helping to bring down costs and increase access to patients.

Third, Mr. Elliott failed to acknowledge that only a few companies are capable of supplying ARVs to 17 million people. The four companies cited – Aurobindo, Cipla, Hetero, and Mylan – are longtime leaders in this space, uniquely investing in the quality, capacity and innovation required to maintain lifelong treatment for every person living with HIV.

For example, these four companies account for 69% of FDA approvals under PEPFAR, which ensures patient safety. Only five companies have approval by the FDA or the World Health Organization (WHO) to supply the most prescribed ARV combination in the world today (TLE).

Likewise, few companies have chosen to invest in the necessary manufacturing capacity. It is well understood that ARV supply depends not only on finished dosage forms (FDF), but on active pharmaceutical ingredient (API). API manufacture requires a distinctive level of capital expenditure. In Mylan’s case, for example, we have invested approximately a quarter billion dollars in both API and FDF production capacity for ARVs.

In terms of innovation, it’s typical that leading suppliers drive R&D to launch novel products, which are later supplied by others. This was the case for TLE, for which Mylan was the only WHO or FDA-approved supplier for three years (during which Mylan reduced its price by 50% with increasing volumes). And this is the case today, with Aurobindo and Mylan submitting for regulatory review the combination of tenofovir, lamivudine and dolutegravir, as recommended by the WHO to improve patient outcomes and reduce program costs. Also recommended by the WHO is a reduced-dosage form of TLE, known as TLE400, for which Mylan recently received FDA approval; in this case, we have actively supplied product samples and provided a right of reference to multiple other companies, so that they too can supply TLE400.

Mylan takes seriously its role to supply ARVs to millions of people living with HIV, and we have consistently argued for evidence-based assessments of supplier performance and of market needs. That is why we welcome rigorously researched analyses and transparent reporting about the ARV market. It’s also why we welcomed the constructive conclusions of the meetings the Global Fund and PEPFAR co-convened in September and November of 2016 to assess the state of the ARV market.

In no case have these assessments raised any “threat of disruption.” To make unfounded and misleading claims and raise unnecessary alarm about the state of the market is deeply at odds with the shared goal in the HIV/AIDS community of achieving access for all. We do not know what motivated Mr. Elliott to publish a commentary so at odds with the truth; we don’t believe that Mr. Elliott’s assertions are supported by the facts.

Mylan remains committed to the fight against HIV/AIDS and looks forward to continuing to serve as a partner to maintain and expand access to treatment for people living with HIV.

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We market a growing portfolio of approximately 7,500 products around the world, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

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