

September 28, 2016

The Honorable Ed Hernandez, O.D.
Twenty-Second Senate District
California State Legislature
State Capitol
Room 2080
Sacramento, California 95814

Dear Senator Hernandez:

We appreciate your interest in Mylan and the concerns related to the pricing and access for our EpiPen® Auto-Injector product.

Before addressing your important questions, we would like to share with you a little background on Mylan. Mylan's success since its founding in 1961 has been built on three principles: producing high quality medicines, significantly expanding access to those medicines, and helping to lower health care costs. Mylan is much more than any one product. We manage a portfolio of more than 2,700 separate products in 165 countries and territories.¹ In the U.S. alone, Mylan sells 21 billion doses annually of 635 products, at an average selling price of \$0.25 per dose across all of our specialty and generic products, including the EpiPen Auto-Injector®.

Approximately 10% of all generics dispensed in the U.S. are Mylan products. Over the last decade, Mylan's medicines have reduced U.S. healthcare costs by approximately \$180 billion. We are able to do this because we have invested significantly in building one of the industry's largest, most efficient and reliable supply chains. Additionally, Mylan has 241 abbreviated new drug applications pending FDA review and multiple biosimilar applications in development to help bring additional competition and further reduce U.S. health care costs.

Now turning to the points raised in your letter. First, with respect to pricing, it should be noted that price increases for EpiPen Auto-Injector have not yielded the revenue to Mylan that many assume. The vast amount of misinformation in the marketplace has left many with the false impression that Mylan is receiving more than \$600 for a two unit package of the EpiPen Auto-Injector. This is not the case and we are working hard to set the record straight.

In the complicated world of pharmaceutical pricing, there is something known as the wholesale acquisition cost ("WAC"). The WAC price of the EpiPen product is \$608 for each pack of two pens, but after paying rebates and various fees, Mylan actually receives, on average, \$274 of the \$608. From \$274, you must subtract our cost of goods, which is \$69, leaving us a balance of \$205. After subtracting all direct EpiPen Auto-Injector product related costs, our net profit is approximately \$100 for a 2unit package or approximately \$50 per pen.² Among other things,

¹ June 30, 2016 Form 10-Q

²See the Current Report on Form 8-K filed with the Securities and Exchange Commission on September 26, 2016.

this profit is used to help fund research and development and to maintain and improve our facilities across Mylan in which we will invest \$1.2 billion this year alone. Mylan's price increase for the EpiPen device were taken over the course of nine years and reflect an investment in improving the product, significantly increasing awareness of anaphylaxis and enhancing access to the product. During this same time period Mylan has invested approximately \$4 billion in research and development and \$2.5 billion in capital expenditures to bring many generics and biosimilars to market and expand our manufacturing capacity.

As anyone who has used the product knows, the EpiPen device we have in the market today is substantially different from the one we acquired. In 2009, we launched a next generation epinephrine auto-injector which represented a complex and innovative re-design of the device, which includes a "Never See" needle among other enhancements. This sterile injectable drug-in-device includes more than 15 critical components and delivers the epinephrine drug within seconds. Also, we continue to invest in product improvements, such as a formulation with a longer shelf life that would extend the period between refills.

Before Mylan acquired the EpiPen Auto-Injector in 2007, there was a deep lack of awareness and barriers to access for epinephrine auto-injectors. Today, more than 2.7 million patients – an increase of 80% since 2007 - have filled prescriptions for epinephrine auto-injectors. While we have significantly enhanced awareness, we realized that there is much more work that needs to be done due to the at-risk population of 43 million.

After acquiring the EpiPenAuto-Injector, Mylan recognized that life threatening allergic reactions can occur quickly and without warning and that epinephrine auto-injectors needed to be as accessible as defibrillators are in public spaces. We saw news reports and heard stories of children dying at school because they did not have access to an epinephrine auto-injector to use on children without a prescription in their name. We saw this as an unacceptable and largely preventable health problem, which is why we partnered with advocacy groups as well as State legislators to advocate for legislation that would permit undesignated epinephrine auto-injectors in schools (a prescription not in a child's name, but rather in a school's name). Today, this is permitted in 48 states.

Recognizing the budgetary hardship faced by schools, we launched the Free EpiPen® (epinephrine injection, USP) Auto-Injector EpiPen4Schools® Program ("EpiPen4Schools") in 2012, which would allow public or private schools the ability to receive four EpiPen devices free of charge, with no strings attached from Mylan. Since 2012 more than 700,000 free EpiPen devices have been distributed, and more than 66,000 schools, approximately half of all U.S. schools, have participated in this program to receive free devices. When a school has need to use our free devices, the school is able to order a free replacement. These facts are important for us to emphasize in response to the particular concern you raised in your letter about the cost burden to schools. It also is important to note that a recent survey of approximately 10% (6,500 schools) participating in the EpiPen4Schools program during the 2013-2014 academic year reported that nearly 400 free EpiPen devices were used in incidents of anaphylaxis. And 25% of the reported anaphylaxis events occurred in individuals with no previously known allergies, underscoring the importance of access to epinephrine auto-injectors in public places.

As of September 26, 10,507 California schools (68.6%) have received free EpiPen devices through this program. And we would welcome the opportunity to work with you to ensure that all schools in California have access to free EpiPen devices through this program.

Additionally, we are continuing our work to expand access to epinephrine in public places such as restaurants, colleges and universities so emergency responders and caregivers are equipped to assist individuals experiencing anaphylaxis in these various settings as well. Again, we want to recognize California's leadership in recently passing legislation to allow public entities to stock and administer epinephrine auto-injectors. Mylan also regularly donates EpiPen devices to a variety of other non-profit organizations, including first responders, summer camps, and community programs.

While we believe our record is good and we have succeeded on many fronts regarding access and awareness, we are not perfect. Given the evolving healthcare landscape we recognized opportunities to improve and acted immediately. While approximately 85% of consumers who are prescribed an EpiPen Auto-Injector have out of pocket costs of less than \$100 for a two unit package and a majority less than \$50, we wish we had been better at anticipating the potential finance issues for the growing minority of patients who don't have access to insurance or a patient access program or who have large deductibles that affect the price they pay for an EpiPen Auto-Injector. We took immediate and unprecedented action to address the problem and to ensure that everyone who needs an EpiPen Auto Injector is able to get one:

- 1) We increased the My EpiPen Savings Card™ program benefit from \$100 to \$300;
- 2) We doubled the eligibility threshold of our Patient Assistance Program to \$97,200 for a family of four;
- 3) We are introducing the first ever generic version of the EpiPen Auto-Injector, cutting the WAC price in half from \$608 to \$300. We anticipate that the generic will capture more than 85% of the market, resulting in a savings to patients and the healthcare system of approximately \$1 billion.

Thank you for the opportunity to respond and we hope that the information provided above has been helpful in addressing questions relating to pricing and access to the EpiPen product. Price and access exist in a balance and we believe that we have and continue to strike that balance. We certainly don't want to go back to a time – not that long ago- when awareness of anaphylaxis was much lower and epinephrine auto-injectors were only available in schools with a prescription for an individual child.

We look forward to a continued partnership and would be happy to address any further questions.