Presidential Candidates Strong Supporters of Greater Access to Generics and Biosimilars

By Dalia Buffery, MA, ABD

At the 2008 Annual Policy Conference of the Generic Pharmaceutical Association (GPhA), held in September in Washington, DC, advisors to the presidential candidates Barack Obama and John McCain told GPhA members that both candidates agree on the urgent need to increase access to generic medications—including generic biologics (referred to as biosimilars or follow-on biologics)—as a way to control the ever-escalating US healthcare costs.

Dora Hughes, Health Policy Advisor to Obama, and Douglas Holtz-Eakin, Senior Policy Advisor to McCain, noted that expanding the use of generics by physicians and by patients is among the top of their healthcare priorities. Kathleen Jaeger, GPhA’s President and CEO, reiterated that message to GPhA members during the meeting, saying, “As American families increasingly struggle with rising healthcare costs, both parties are talking about increasing access to affordable generic—and biogeneric—medicines.”

“We know that expanding the use of generics and eliminating barriers to that goal must be a centerpiece of any health reform effort,” said Ms Hughes at the meeting, elaborating on Obama’s position. Commenting on McCain’s approach to generics, Mr Holtz-Eakin noted, “Controlling healthcare costs has to be the imperative of any effective healthcare reform.”

Both Ms Hughes and Mr Holtz-Eakin said that the 2 candidates recommend that the US Food and Drug Administration (FDA) should move as fast as possible to make biologic agents available as generics, believing that the 14-year period of exclusivity that had been suggested by pharmaceutical companies is much too long, and that their respective candidates support a much shorter exclusivity period. According to Mr Holtz-Eakin, “Senator McCain’s instincts are to make the period as short as possible so that you can get products to market more quickly.” As for Obama’s approach, noted Ms Hughes, “14 years (of data exclusivity), as requested by the biotech industry, is excessively long...we’re tilted toward the shorter period.”

There is currently no pathway for an FDA approval process of biosimilars in the United States. Several proposals that were put up for debate in Congress last year were rejected for one reason or another, all reflecting a basic disagreement between traditional pharmaceutical and generic drug manufacturers. An article published in Pharmaceutical Business Review Online notes that “it is now likely that the legislative pathway allowing approval of biosimilars will be in place by the end of 2010.” The author adds, “Given the potential influence of a new president, the exclusivity period for biologics may be significantly shorter than the 14 years that the branded firms are hoping for.”

With the continuing increase in the number and cost of biologic agents, setting a new pathway for an FDA approval process for biosimilars may soon become a reality in the new administration, regardless of who the president is.

References