

Bayer HealthCare

March 30, 2011

Commander Krista Pedley, PharmD, MS
Director
Office of Pharmacy Affairs
Health Resource and Services Administration
Department of Health and Human Services
5600 Fishers Lane, Parklawn Building, Mail Stop 10C-03
Rockville, Maryland 20857

Open Letter to HRSA Office of Pharmacy Affairs Regarding the Yaz® Limited Distribution System

Dear Commander Pedley:

Bayer HealthCare Pharmaceuticals Inc. (“Bayer”) distributes Yaz®, an oral contraceptive used by millions of women in the United States.

Beginning with the second quarter of 2011, we anticipate that we will be unable to meet demand for Yaz®. On April 1, 2011, Yaz® will become subject to the 340B program’s “penny pricing” policy, which will make the 340B ceiling price for the product \$0.01 per tablet.¹ As a result, based on our past experience, we expect a substantial increase in ordering activity for Yaz®. Bayer is unlikely to be able to significantly increase its supply of Yaz® in excess of previously forecasted demand in order to fill these much larger orders. Therefore, in an effort to ensure that all of our customers have an equal opportunity to meet their future needs for Yaz®, beginning in the second quarter of 2011, we are instituting a limited distribution system for the product. The limited distribution system will impact all customers in a fair and consistent fashion, and we anticipate that this system will remain in place for the foreseeable future.

This limited distribution system will apply to all orders for Yaz® received on or after April 1, 2011, and will limit the amount of Yaz® any customer (340B, commercial, or other) may purchase to that customer’s historical average quarterly ordering volume on a percentage basis applied to the then current quarter’s available supply. This system is substantially similar to the system we put in place for Yasmin® in the fourth quarter of 2008 when faced with similar circumstances, and it will affect all Yaz® customers, including 340B covered entities equally, in the same manner.

Based on our review of the Guidance received from the Office of Pharmacy Affairs (“OPA”), this system complies with the relevant 340B program guidance. Please feel free to share this letter and the information contained herein with 340B covered entities and other interested parties as you think appropriate.

¹ The \$0.01 340B ceiling price results from the requirement that brand manufacturers include the best price of an authorized generic in the Best Price of the branded product.

Yaz® Limited Distribution System

Beginning with the second quarter of 2011, Bayer will implement a limited distribution system for Yaz®, which will limit the number of Yaz® cycles available to each United States' customer. The cycles of the product available to each customer will be limited to that customer's average quarterly purchase volume in the last two quarters of 2010 (i.e. between July 1, 2010 and December 31, 2010) based on a percentage basis then applied to the current quarter's available supply. This percentage-based allocation system will provide Bayer with some flexibility to adjust the maximum available cycles of Yaz® each customer may order based on changes in the available supply of Yaz®, as they may occur, while maintaining equity among all of our customers.

Under this limited distribution system, customers' orders for Yaz® will be filled on a first-in, first-out ("FIFO") basis, until a customer reaches its predetermined limit for the quarter. A customer that reaches its quarterly limit may place additional orders for Yaz® at the beginning of the subsequent quarter (subject, of course, to that subsequent quarter's limit). Bayer will not require minimum purchase amounts per transaction, and importantly, a customer's 340B participation status and the price a customer pays for Yaz® will not affect its quarterly allotment.

We have calculated the average quarterly Yaz® purchasing volume for each customer who purchased the product in the last half of 2010 (from July 1, 2010 to December 31, 2010). For customers with no purchases of Yaz® in the second half of 2010, Bayer will establish a maximum order quantity based on the overall average quarterly purchase volume of customers in that new purchaser's class of trade. We will apply this average equally to all such customers.

Customers may continue to order Yaz through their normal distribution pathway (either direct from Bayer or through a wholesaler) under the limited distribution system. We will advise wholesalers of the purchasing limits and will ask wholesalers to accordingly limit Yaz® sales to all of their customers. We will also immediately notify existing direct customers of the distribution system.

Conclusion

Bayer is committed to making our products, including Yaz®, available through the 340B program at appropriately discounted prices. Without implementing a limited distribution system, based on past experience and current supply forecasts, we anticipate a distribution problem which could prevent millions of women from obtaining Yaz® from their customary healthcare provider. Beginning with the second quarter of 2011, equitable and non-discriminatory restrictions on Yaz® purchasing will ensure that 340B covered entities, as well as the Medicaid program, the Department of Veteran Affairs and Federal Supply Schedule entities, are able to purchase Yaz®. We are implementing this limited distribution system to best ensure that all of our customers and all of their Yaz® patients have equal access to the product while the 340B penny price is in effect.

Bayer appreciates the Office of Pharmacy Affairs' cooperation during this period.

Very Truly Yours,

BAYER HEALTHCARE PHARMACEUTICALS INC.

Christopher Jackson