A Meeting, a MaPP, and Two Lists: Initial Elements of the Commissioner's Drug Competition Action Plan Rolled Out

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Background

FDA has been busy recently in areas related to drug pricing. In the last half of June, FDA issued a public meeting notice, a revised Manual of Policy and Procedures (MaPP), and two lists of approved drugs for which a generic has not been approved. As more than one senior Food and Drug Administration official has testified at Congress or otherwise communicated to members of the public, patient advocacy groups and others, FDA does not regulate drug prices. Nevertheless, on June 21, 2017, Commissioner Scott Gottlieb announced that the agency is working on a Drug Competition Action Plan to facilitate competition through the approval of generic drug products which, in turn, may help bring down prices. FDA has not revealed a full action plan, but the first few components have been announced and it's clear this area has the Commissioner's full attention.

Public Meeting

After Commissioner Gottlieb's announcement, FDA published a notice of a public meeting to be held on July 18, 2017, entitled "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access."[1] The meeting should provide the public with an opportunity to submit comments on Hatch-Waxman administration to help ensure the intended balance between encouraging innovation and accelerating the availability of lower cost alternatives is maintained.

Although FDA will receive any relevant input from stakeholders, the meeting notice includes a series of questions on which the agency is specifically seeking input, including questions about what actions FDA should take to promote access to innovator drugs subject to Risk Evaluation and Mitigation Strategies (REMS). Commissioner Gottlieb has specifically noted this particular issue and that, "in some cases, branded companies may be using regulatory strategies or commercial techniques to deliberately try to block," generics from obtaining necessary samples.

AGG Observations

- While it's nothing new to hear allegations of branded companies refusing to allow access to products, the new Commissioner has made it clear that this is a topic he's making a priority. The time is ripe (overripe, some may say) for intervention.
- Even those companies who have been in contact with FDA about obstacles encountered in obtaining access to testing samples of branded drugs necessary for generic drug development will want to submit a comment to this meeting docket.

Updated MaPP

FDA announced an update to the Office of Generic Drugs (OGD) MaPP, formerly known as the *Review Order of Original ANDAs, Amendments, and Supplements*, and now entitled *Prioritization*

1 Announcement available at https://www.gpo.gov/fdsys/pkg/FR-2017-06-22/pdf/2017-12641.pdf. The deadline for submitting comments is September 18, 2017.

of the Review of Original ANDAs, Amendments, and Supplements, effective June 27, 2017.[2] The newly revised MaPP provides certain modifications to OGD's previous approach of "first-in, first-reviewed," and sets forth criteria for "expedited review." Most significant, applications for generic products for which there are fewer than three abbreviated new drug applications (ANDAs) approved and for which there are no blocking patents or exclusivities may receive expedited review. This represents a change from the previous practice of prioritizing review of only the first generic. FDA made the decision to change the focus from the first generic to the first three generics based on data that indicate that significant price reductions occur when there are multiple FDA-approved generics available.

The MaPP also states that certain submissions including those related to: (1) drug shortages, (2) special review programs (e.g., President's Emergency Plan for AIDS Relief), (3) public health emergencies, or (4) sole source drugs, among others enumerated in the MaPP, may receive expedited review.

FDA will not consider expedited review for submissions involving facilities that are subject to an Official Action Indicated (OAI) recommendation (except in cases where FDA determines expedition is necessary to address a public health concern).

AGG Observations

- Under the revised MaPP, the criteria apply "at all stages of review." This means that FDA may determine that a submission which is not a candidate for expedited review at the time it is received could be eligible for expedited review later in the review process. It also means that submissions made before the MaPP was revised may be eligible. Companies with pending ANDAs for drugs with fewer than three approved generics may want to consider submitting a request for expedited review.
- The MaPP includes information about how to request expedited review and makes clear that FDA will not make a determination before the relevant submission is received.
- We note that the MaPP speaks in terms of how many approved generics exist, rather than whether those approved generics are marketed. It will be interesting to see how the agency approaches an ANDA for a product for which there are three or more approved ANDAs, but fewer than three marketed.
- The Generic Drug User Fee Act (GDUFA) II is still under consideration at Congress and includes the concept of a priority review that is two months shorter than the normal review period. The updated MaPP states that all determinations regarding priority of submissions will be consistent with GDUFA. Presumably, this will be amended to reference GDUFA II once it passes, or at least will be interpreted that way.

The Lists

In order to encourage generic drug development, FDA posted a list of approved drugs that have no approved generics and no unexpired marketing exclusivity or listed patents.[3] Part I of the list identifies drug products for which FDA says it "could immediately accept an ANDA without prior discussion." Part II identifies drug products involving "potential legal, regulatory, or scientific issues which should be addressed with the Agency prior to submission of an ANDA." Initial inquiries about Part II drug products should be sent to OGD at genericdrugs@fda.hhs.gov.

AGG Observation

- FDA's stated reason for publishing the list is to improve transparency and encourage generic drug development and the submission of ANDAs. Part II of the list may also serve as an early warning for these drugs with potential issues. Companies already developing ANDAs for these drugs that haven't already spoken with OGD will want to check to see if their candidate is listed. While certainly not a death knell, listing on Part II means there may be more to learn that could be a bad omen of things to come or a good thing, and FDA has now provided a way to find out more.

2 MaPP 5240.3 Rev. 3 available at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf.

3 https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/UCM564441.pdf.

Conclusion

It will be interesting to see what the other elements of the Drug Competition Action Plan are and when they will be released. Stay tuned.

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