FDA – Industry MDUFA V Reauthorization Meeting
February 22, 2022, 3:00 pm – 5:15 pm EST
Virtual Via Zoom

Purpose

To discuss MDUFA V reauthorization.

Attendees

FDA

- Lauren Roth*, OC OP*
- Sara Aguel*, CDRH*
- Cherron Blakely*, CDRH*
- Kathryn Capanna*, CDRH*
- Josh Chetta, *CDRH*
- Owen Faris, *CDRH*
- Misti Malone*, CDRH*
- Jonathan Sauer*, CDRH*
- Don St. Pierre, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman*, CDRH*
- Cherie Ward-Peralta*, CBER*
- Angela Granum, *CBER*
- Claire Davies*, OCC*
- Louise Howe, *OCC*
- Emily Galloway, *OC Econ*
- Malcolm Bertoni*, Consultant*
- Nia Benjamin, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*

Industry

AdvaMed Team

- Janet Trunzo, *AdvaMed*
- Zach Rothstein*, AdvaMed*
- Nathan Brown*, Akin Gump*
- Phil Desjardins*, Johnson & Johnson*
- Danelle Miller, *Roche*
- Michael Pfleger*, Alcon*
- Nicole Taylor Smith*, Medtronic*

MITA Team

- Peter Weems, *MITA*
- Diane Wurzburger*, GE Healthcare*
- Elisabeth George, *Philips*
- Nicole Zuk*, Siemens Healthineers*

MDMA Team

- Mark Leahey, *MDMA*
- Melanie Raska*, Boston Scientific*

ACLA Team

- Thomas Sparkman, *ACLA*
- Don Horton, *Labcorp*
- Shannon Bennett*, Mayo Clinic Laboratories*

Meeting Start Time: 3:00 pm EST

Executive Summary

During the February 22, 2022 user fee negotiation meeting, FDA and Industry discussed the financial framework that was supported by two trade associations, AdvaMed and MITA. The Agency described the work to evaluate potential performance goals, workload projections, and associated resource estimates that would support the framework, and which contributed to FDA's conclusion that this framework was a workable compromise that the Agency could agree to in principle.

Proposal Components

Financial Overview: The proposal involved two scenarios—a "guaranteed funding" scenario, and a scenario in which the Agency received "add-on" payments if specified performance goals were met. Under the guaranteed funding scenario, the five-year total user fee revenue would be $1,721,430,700. Under a scenario in which all performance goals were met, the five-year total target user fee revenue would be $1,975,202,000. The amount of user fee revenue could fall within these boundaries, if some but not all performance goals were met, resulting in some but not all of the add-on payments being received.

Add-on Fees: The proposal contemplated add-on fees to enhance accountability for meeting specified performance goals. In addition, if goals were met, this structure would provide resources that supported further improvement in the goals. FDA noted that this feature of the proposal—that add-on payments would be applied to achieve specified performance improvement—was critical to FDA's perspective that the add-on payment concept could fit within the user fee structure. The proposal contemplated that add-on payments would be available if performance goals were met in the following areas: pre-submissions; de novo requests; 510(k) submissions; and PMA submissions.

Pre-submissions: Pre-submission resource estimates reflected the following conditions:

- Guaranteed funding scenario:
    - FY23: 75% of Pre-submission requests would receive feedback within 70 days.
    - FY24: 85% of Pre-submission requests would receive feedback within 70 days.
    - FY25-27: 90% of Pre-submission requests would receive feedback within 70 days.
- During years in which add-on payments are not applied, the Pre-submission goal would be capped at 4,300 submissions, except for Pre-submissions associated with Breakthrough-designated products or products included in the Safer Technologies Program (STeP). Any other Pre-submissions above the cap would receive feedback as resources permit.
- During any years in which Pre-submission add-on payments are applied, the Pre-submission goal would be capped at an escalating number of 4,700 (in FY25), 4,800 (in FY26), and 4,900 (in FY27) Pre-submissions, except for Pre-submissions associated with Breakthrough-designated products or products included in STeP. Any other Pre-submissions above the cap would receive feedback as resources permit.
- Timing:
    - If agreed-upon goals were met in FY23, FDA would receive add-on payments to support improved performance beginning in FY25.
    - If agreed-upon goals were met in FY24, FDA would receive add-on payments to support improved performance beginning in FY26.
    - If agreed-upon goals were met in FY25, FDA would receive add-on payments to support improved performance beginning in FY27.

De Novo requests: Resource estimates related to the De Novo decision day goal reflected the following conditions:

- For guaranteed base funding, 70% of De Novo submissions will receive a decision within 150 FDA days.
- If the De Novo decision goal is met for FY23 submissions, FDA will receive add-on payments to support improved performance; beginning in FY26, the goal will be set that 80% of De Novo submissions will receive a decision within 150 FDA days.
- If the De Novo decision goal is met for FY24 submissions, FDA will receive add-on payments to support improved performance; beginning in FY27, the goal will be set that 90% of De Novo submissions will receive a decision within 150 FDA days.

510(k) submissions:

- For guaranteed base funding:
    - The Shared Outcome Total Time to Decision (TTD) goal would be: FY23: 135 days; FY24: 124 days; FY25-27: 112 days; and,
    - The FDA decision day goal would be that FDA will issue a MDUFA decision for 95% of 510(k) submissions within 90 days.
- If the 510(k) goals were to be achieved for FY23, then add-on payments would be applied in FY26 and the 510(k) TTD goal would be set to 108 days. If the 510(k) goals were to be achieved in FY24, then add-on payments would be applied in FY27 and the 510(k) TTD goal would be set to 108 days.
- 510(k) submissions with extended holds (i.e., >180-days), if any, would be excluded from the cohort. The standard 2% trim would be applied to the top and bottom of the cohort. A 1% increase in trim would be applied if any MDUFA V cohort were to exceed the FY22 cohort by 5%.
- In FY23, Industry will hold a publicly available educational webinar, in which FDA will participate, on utilizing the e-STAR format for 510(k) submissions to encourage its use and adoption.
- FDA also described an alternative option for the TTD goal under the guaranteed funding scenario by applying a 5% trim to the long-running portion of the cohort for FY23-24. Under this alternative option, the TTD goals for FY23-FY24 would be the following: FY23: 128 days and FY24: 122 days.

PMA submissions:

- For guaranteed base funding:
    - The TTD goal would be: FY23: 290 days; FY24: 290 days; FY25-27: 285 days; and
    - The FDA decision day goal would be that, for submissions not requiring advisory committee input, FDA will issue a MDUFA decision for 90% of PMAs within 180 days.
- If the PMA goals were to be achieved for FY23, then add-on payments would be applied in FY26 and the PMA TTD goal would be set to 275 days. If the PMA goals were to be achieved for FY24, then add-on payments would be applied in FY27 and the

PMA TTD goal would be set to 270 days.

Other performance goals:

- FDA would provide a statement for the basis of a deficiency 75/80/85/90/95% of the time for fiscal years FY23/24/25/26/27 respectively.
- Other review performance goals under the MDUFA IV Commitment would remain the same.

TAP Pilot: FDA would initiate a TAP Pilot beginning in FY23.

- The pilot would be scoped to include the following:
    - In FY23, enroll up to 15 products in a "soft launch" in one Office of Health Technology (OHT);
    - In FY24, continue to support products enrolled in the previous fiscal year and expand to enroll up to 45 additional products in two OHTs (i.e., up to 60 total products enrolled across all fiscal years and OHTs); and
    - In FY25, continue to support products enrolled in previous fiscal years and expand to enroll up to 65 additional products in four OHTs (i.e., up to 125 total products enrolled across all fiscal years and OHTs).
- Agreed upon success measures would be used to evaluate the success of the TAP pilot. FDA proposed that success measures would include achievement of specified review performance goals for FY23 and FY24 and responding 90% of requests for interactions and written feedback from TAP pilot participants within specified timeframes. If success measures were demonstrated in an initial, midterm assessment (to occur in FY25), add-on payments would be applied in FY26. If success measures were demonstrated in a second assessment (to occur in FY26), add-on payments would be applied in FY27. If success measures were not demonstrated in the assessments, the pilot would sunset.
- FDA would use the FY26 add-on payment to continue to support products enrolled in previous fiscal years and expand the pilot to enroll up to 120 additional products across all OHTs (i.e., up to 245 total products enrolled). FDA would use the FY27 add-on payment to continue to support products enrolled in previous fiscal years and expand the pilot to include up to 130 additional products (i.e., up to 375 total products enrolled).
- FDA would engage an independent third party to conduct a survey to assess pilot participant experience, which would help FDA improve implementation of the pilot.

Other programmatic enhancements: The proposal included cost estimates for new user fees to support expansion of the Patient Science and Engagement, Standards, and International Harmonization programs that were consistent with FDA's proposal of November 18th proposal. Likewise, the proposal included cost estimates for user fees to support one-time costs for real world evidence, recruitment, and two independent assessments, consistent with FDA's November 18th proposal. It also reflected use of carryover balance funds to maintain the Third Party Review Program.

Operating Costs: The framework included operating costs in four categories: (1) Review performance (i.e., associated with the pre-submissions and back-to-basics/fill MDUFA IV gaps

estimates); (2) the TAP Pilot; (3) Patient Science and Engagement, and (4) Standards. In response to Industry questions, FDA provided a breakdown of the operating costs associated with the payroll gap.

Financial assumptions: The proposal reflected a cost per FTE of $291,509, as well as savings from application of the quarterly on-boarding assumption. FDA indicated that the Agency would support a 2% cap on the growth in the CPI component of the inflation adjustment formula for FY21-23.

Carryover balance: The proposal reflected application of approximately $100 million in funds in the existing carryover balance to offset the cost of MDUFA V. Approximately $8.6 million was estimated for the cost to begin hiring in FY22 in the areas in which the need is greatest to support the program. This would support filling 42 new positions. Approximately $90.6 M was included in the framework to offset submission and facility registration fees in the FY23.

In addition, as an additional accountability measure related to the carryover balance, FDA noted that it could agree to a ceiling on the carryover balance (i.e., funds "available for use") of 13-weeks—meaning, the carryover balance were to exceed 13 weeks of operating reserve funding, FDA would decrease registration fee revenue to bring down the balance below the ceiling. This proposal would be consistent with the carryover balance structure of other human medical product user fee agreements.

Hiring: FDA noted that it would support the following hiring accountability measures:

- The Commitment Letter would establish annual hiring targets for new positions, and there would be a future fee offset if the targets were missed. If the target were to be missed by more than 15% for FY23 and more than 10% for future years, unused funds that were projected for these positions for that year would be used to offset facility registration fees in the next annual fee setting cycle. FDA noted that the formula for calculating the amount of the offset would need to take into account the quarterly on-boarding assumption that was applied to estimate user fee revenue for new hires.
- FDA would retain an independent contractor to conduct a MDUFA Workforce Data Assessment, as described in FDA's November 18th proposal.

Update to Appropriations Trigger: FDA noted that it would support recommending an update to the legal condition for the MDUFA program that specifies the minimum amount to be appropriated for devices and radiological health.

Discussion

Industry appreciated FDA providing additional details regarding concepts that had been discussed at previous negotiation meetings or informally.

ACLA requested verification regarding the inclusion of laboratory developed tests (LDTs) in the workload assessment for Pre-submissions. FDA indicated that cost estimates presented for Pre-submissions did not include a significant increase in LDT submissions.

Industry noted that the proposed PMA TTD goals would represent worse performance than actual pre-COVID performance. Because the pre-COVID performance exceeded the MDUFA IV performance goal, FDA responded that it could not agree to a goal based on pre-COVID performance because FDA personnel were overworked.

Meeting End Time: 5:15 pm EST