Stakeholder Consultation Meeting on MDUFA V Reauthorization
March 29, 2022, 12:30-2:00 PM
Virtual via Zoom

Purpose

To provide a status update on the conclusion of MDUFA V negotiations and summarize the proposed MDUFA V recommendations.

Summary of Proposed MDUFA V Recommendations

FDA shared that MDUFA V negotiations have concluded, that the proposed commitment letter is available for public comment, and this meeting would be the last stakeholder consultation meeting. FDA summarized the overall themes in the proposed MDUFA V commitment letter, including significant new or modified recommendations related to review goals, program improvements, and additional transparency and accountability measures with respect to MDUFA V finances and hiring.

Review Performance

FDA described the MDUFA V review performance goals, with a focus on the 510(k) and PMA Shared Outcome Total Time to Decision Goals, De Novo Decision Goal, and Pre-Submission Written Feedback Goal. FDA noted that other review performance goals are continued from the MDUFA IV agreement. FDA explained that there will be opportunities for "add-on" payments to further improve specified review goals if certain review performance and/or shared outcome goals are met for FY 2023, 2024, and/or 2025.

Program Improvements

FDA summarized the commitments related to MDUFA program improvements, including:

- Launch the Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot, a voluntary pilot program to provide earlier and more frequent interactions with FDA and facilitate coordination of earlier and more strategic stakeholder input.
- Increase support for the Patient Science and Engagement Program to continue engaging patients and incorporating their perspectives in the regulatory process by facilitating patient engagement through patient-friendly educational content; exploring ways to advance health equity by incorporating data and perspectives from diverse patients, expanding patient science review expertise and capacity; sharing examples; holding a public meeting on patient-generated health data (PGHD) for collecting COA data and for remote clinical trials; and issuing draft guidance on incorporating clinical outcome assessments (COA) into premarket studies and update patient preference information (PPI) guidance.
- Enhance international harmonization activities by expanding engagement in international harmonization and convergence efforts to promote alignment with international best practices and internationally developed policies.
- Continue development of Real-World Data and Real-World Evidence methods and policies to advance regulatory acceptance for premarket submissions, including expanded indications for use and new clearance/approval of new devices, and clarify related reporting requirements.

- Continue support for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program during MDUFA IV to transition from a pilot to a sustainable and expanded program.
- Continue building digital health expertise and continue working to streamline and align FDA review processes with software lifecycles for digital health products.
- Continue to support the Third Party Review Program with carryover balance funds from MDUFA IV.
- Improve communication in FDA deficiency letters by clarifying what constitutes a statement of the basis for the deficiency in updated guidance, training staff and managers on the updated guidance, and establishing a related performance goal.
- Continue to enhance IT infrastructure to support the process for the review of device applications, including improving a submission progress tracking system and developing electronic submission templates for more submission types.

Financial Transparency and Hiring

FDA listed several new steps to provide additional transparency and accountability measures with respect to MDUFA V finances and hiring. FDA will publish a MDUFA 5-year financial plan that will be updated annually. FDA will use carryover funds to support MDUFA V programs and establish a ceiling of 13 weeks for other operating reserves in the carryover. FDA will use user fee revenue to fund strategic hiring and retention and will set annual hiring targets with a fee reduction if minimum hiring goals are not met. In addition to regular audits by the CDRH Quality Management and Organizational Excellence staff, there will be two independent assessments, to assess current methodologies and data/metrics available to represent the MDUFA workforce, and to assess the process for the review of device applications.

Stakeholder Questions and Feedback

FDA responded to questions and comments from stakeholders regarding review goals, creation of patient-friendly materials to facilitate patient engagement, engagement of patients from underserved communities, opportunities for FDA to encourage greater patient engagement in other countries, development of real-world evidence, and accreditation of third-party review organizations. Stakeholders expressed appreciation for the robust inclusion of patient science and engagement in this effort and FDA's commitment to including patient insights in the regulatory process.

To close the meeting, FDA explained the next steps with respect to the proposed recommendations and plans for a public meeting in April.

Attendees:

Stakeholders

- Michael Ward, *Alliance for Aging Research*
- Alix Braun, *American Academy of Orthopedic Surgeons*
- Paul Conway, *American Association of Kidney Patients*

- Catherine Hill, *American Association of Neurological Surgeons / Congress of Neurological Surgeons*
- Maria Gmitro, *Breast Implant Safety Alliance*
- Marcia Howard, *Consumer Healthcare Products Association*
- Dylan Simon, *EveryLife Foundation for Rare Diseases*
- Amy Ohmer, *International Children's Advisory Network*
- Leanne West, *International Children's Advisory Network*
- Paul Melmeyer, *Muscular Dystrophy Association*
- Thomas Eagen, *National Center for Health Research*
- Diana Zuckerman, *National Center for Health Research*
- Jennifer Dexter, *National Health Council*
- Madris Kinard, *Patient Safety Action Network*
- Lisa McGiffert, *Patient Safety Action Network*
- David Davenport, *Personalized Medicine Coalition*
- Cara Tenenbaum, *Postpartum Pelvic Health Advocates*
- Michael Abrams, *Public Citizen*

FDA

- Lauren Roth, *OC OP, Lead Negotiator*
- Cherron Blakely, *CDRH*
- Kathryn Capanna, *CDRH*
- Josh Chetta, *CDRH*
- Misti Malone, *CDRH*
- Michelle Tarver, *CDRH*
- Barbara Zimmerman, *CDRH*
- Malcolm Bertoni, *Consultant*
- Cherie Ward-Peralta, *CBER*
- Louise Howe, *OCC*
- Jennifer Tomasello, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*
- Sharon Davis, *CDRH*
- Mimi Nguyen, *CDRH*
- Andrea Gray, *CBER*
- Felipe Aguel, *CDRH*
- Melissa Torres, *CDRH*