International Engagement with OGD Parallel Scientific Advice (PSA) Process

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Learning Objectives

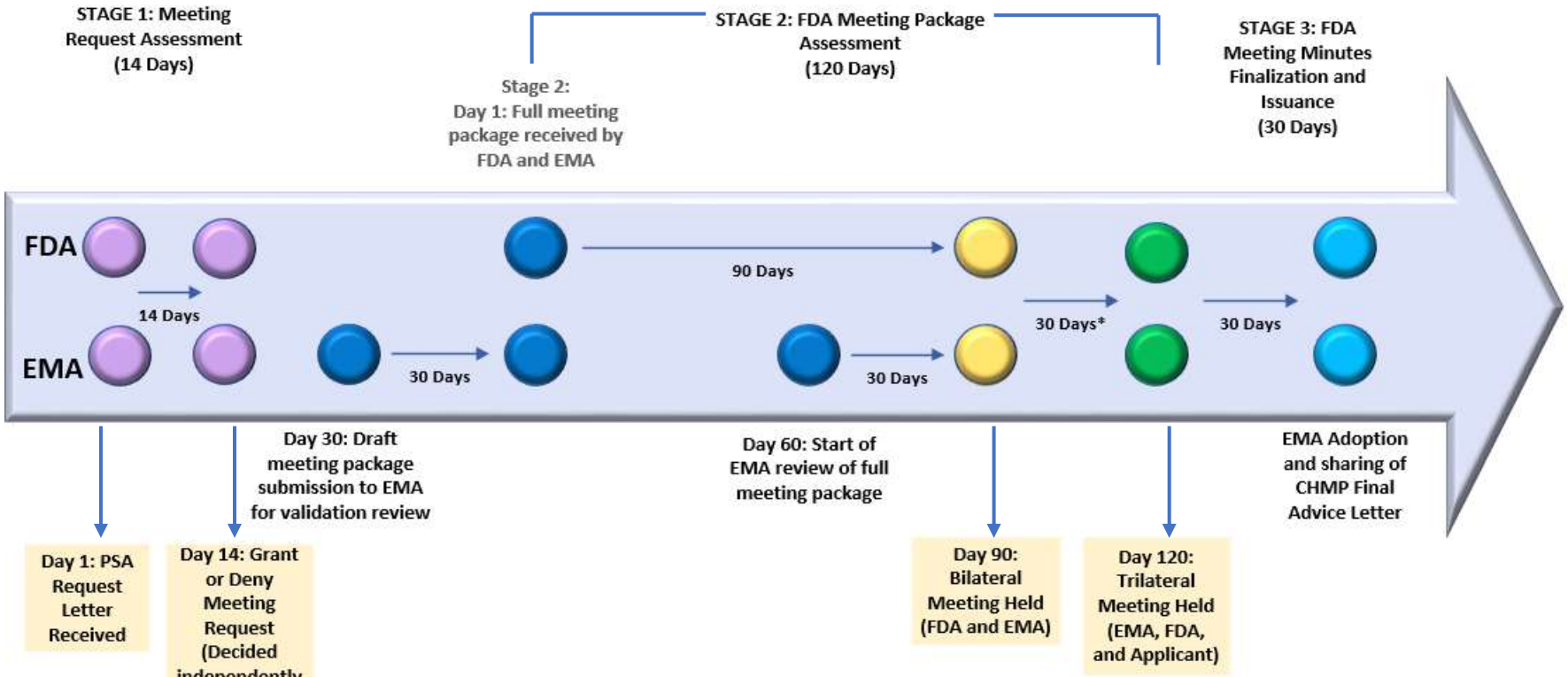
- Outlining the Parallel Scientific Advice (PSA) Process Flow and Timeline
- Describing Advantages for Submitting your PSA Meeting
- Preparing your PSA Meeting Request Package
- Scheduling your Trilateral PSA Meeting
- Understanding Communications Between FDA and the Prospective Applicant

PSA Process

- The PSA process for complex generics/hybrid products is designed to align the process and timeline of FDA's pre-ANDA product development meeting, **as much as possible**, with the process and timeline recommended by EMA's Scientific Advice Working Party (SAWP) for their Scientific Advice (SA) process

  PSA General Principles document

EMA – FDA PSA Pilot for Complex Generic Drug Products/Hybrid Products Timeline



* EMA list of issues for discussion and FDA preliminary responses sent to the applicant ~14 days before the trilateral meeting.

Advantages for Submitting Your PSA Meeting

- Increase dialogue between the two agencies
- Optimize global product development program by enabling discussion of specific questions concurrently with both agencies
- Provide a more comprehensive understanding of the basis for regulatory decisions from both agencies
- Drive convergency helping avoid redundant replication of work or unnecessary diverse testing methodologies
- Shorten the time to drug development and approval

Submitting Your PSA

- Submit a single “Request for PSA” letter (i.e., justification letter) to both EMA: emainternational@ema.europa.eu and FDA: preANDAHelp@fda.hhs.gov
- **Do not** submit the same meeting package through both PSA and FDA’s pre-ANDA program at the same time
- Provide a statement indicating whether the submission is by the prospective applicant or by U.S. agent
- If not based in the U.S., provide the U.S. agent information (including letter of authorization)

Submitting Your PSA

In your justification letter provide:

- Pre-assigned ANDA number*
- Reference listed drug (RLD) information
- Application information (i.e., brief history and status of product development)
- Contact person name and information (applicant or U.S. Agent)
- Purpose and objectives and why a meeting with EMA and FDA is beneficial
- Specific questions and supporting data/information
- Anticipated submission date of full meeting package, if granted
- Explicit authorization for the agencies' comprehensive exchange of all information relevant to the product, including trade secret information (as defined by U.S. statute)

*Information on requesting a pre-assigned number: https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/requesting-pre-assigned-application-number

PSA Process – Stage 1 (14 days)

- FDA and EMA acknowledge, accept and grant or deny your meeting request
- Grant/deny decision - 14 days from date of acceptance
- If denied, FDA provides a path forward (i.e., pre-ANDA product development meeting or controlled correspondence)
- If granted, between Stages 1 and 2:
  - A multidisciplinary team is assigned
  - EMA works with you to validate the meeting package

PSA Process – Stage 2 (120 days)

- A validated final meeting package is received by both FDA and EMA
- By Day 90*, EMA and FDA meet to discuss your meeting package and come to consensus where possible
- FDA issues preliminary responses and EMA sends a list of issues letter approximately 14 days prior to the trilateral meeting
- By Day 120*, a trilateral PSA videoconference meeting is held between EMA, FDA, and the prospective applicant

* Day 90 and day 120 are approximate dates in the timeline

Scheduling and Holding the Trilateral PSA Meeting

- Meeting dates determined by annual SAWP meeting schedule and FDA assessment team availability
- An FDA and EMA meeting project manager are assigned to assist with trilateral scheduling and prospective applicant communications
- Both agencies strive to provide PSA responses that are convergent

PSA Process – Stage 3 (30 days)

- You can submit a summary of the meeting discussion 7 days from the trilateral meeting date
- FDA finalizes and issues meeting minutes, and EMA adopts and sends their CHMP final advice letter approximately 30 days from trilateral meeting date
- After the PSA meeting, each agency retains its individual regulatory decision-making and provides the prospective applicant with independent advice on questions posed during the PSA meeting

CHMP: Committee for Medicinal Products for Human Use

Communications Between FDA and the Prospective Applicant

- FDA communicates and issues correspondences via email
- Acknowledge receipt and acceptance of your submission
- Issues either grant or denial letter
- If granted, issues a meeting information letter with meeting details
- If needed, issues an information request letter (FDA only)
- FDA issues preliminary response letter (approximately 14 days prior to trilateral meeting date) (EMA issues a list of issues)
- FDA issues meeting minutes letter (approximately 30 days after trilateral meeting)

Summary

- A PSA meeting will help optimize your global product development program by enhancing scientific discussion of specific questions with both agencies
- The PSA process closely models the pre-ANDA product development meeting and EMA SAWP process
- A trilateral meeting is generally held within 120 calendar days of acceptance/validation of your full meeting package
- After the PSA meeting, each agency provides you with independent advice on questions posted during the PSA meeting

References

- FDA-EMA Parallel Scientific Advice Pilot Program for Complex Generic/Hybrid Products | FDA
- Global Generic Drug Affairs | FDA
- Questions about the program may be directed to preANDAHelp@fda.hhs.gov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