CMC NA Strategy Forum: Regulators' Pre-session

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Vision

- Working-level perspectives are often not reflected in the dialogue around collaborative approaches and working-level relationships are often not developed
- Working-level staff often do not have the opportunity to hear feedback from industry
- CASSS meetings have provided a venue to support the growth of working-level relationships, interact with industry, and the value working-level conversations
- These conversations highlighted the potential of fostering working-level interactions across regulatory agencies to optimize existing frameworks and identifying unexploited opportunities

Question: *Was there an opportunity to host a regulators' meeting during the CASSS meeting in Ottawa*?

- Could we leverage the on-site presence of regulators and industry to facilitate a conversation on timely issues?
- Could we use this as an opportunity to grow some working-level relationships that might foster avenues to support harmonization?
- Could we use this as an opportunity for industry to share their experiences using collaborate approaches?
- Would CASSS be willing to help facilitate this meeting?

Objectives and Goals

- Bring together reviewers/assessors from different regulatory authorities for an informal conversation around collaborative approaches
  - Build relationships and understanding
- Evaluate the current collaborative initiatives (Access, ICMRA, ORBIS) from a CMC perspective
  - Identify successes and challenges
- Develop tangible, actionable, and meaningful strategies to enhance regulatory collaborations
  - Define outcomes and approaches

Format

- Day before the CMC NA Strategy Forum meeting in Ottawa
- In-person and virtual attendance
- Invitations sent to multiple regulatory authorities
  - Health Canada, SwissMedic, MHRA, TGA, and FDA indicated they were interested in participating
  - Other regulatory agencies cited resource constraints and timing for not participating
- Industry was invited to present case studies on collaborative review
  - What was the filing strategy, what worked well, what was challenging?
  - What message would you like to leave with the regulators?

Overview of the Day

- Morning Session
  - Introductions
  - Industry case studies and discussion
  - Discussion on CMC-specific barriers to effective collaborations
- Afternoon Session
  - Identifying collaborative solutions
  - Preparing a road map
- Read-out
  - Summary slide deck to be shared in Session 2 of the CMC NA Strategy Forum Meeting

Morning Session – Industry Case Studies

- 3 case studies presented by industry representatives
  - John Armando & Susanne Ausborn : *Roche*
  - Patrick McGeehan : *AstraZeneca*
  - Maegan Hollingsworth & Megan Wong : *Eli Lilly and Company*
- Conversations were open, transparent, and very productive
- The case studies highlighted multiple collaborative/reliance approaches
  - Access, ICMRA, EMA Open, Unilateral Reliance, ORBIS
- Presentations were 15 minutes with 30-45 minutes of discussion
- Common themes emerged very quickly

Morning Session – Common Themes

- Everyone wants to do more collaboration but are struggling with ‘how’
- Post-approval changes are 60-80% of the submissions and collaborative approaches are mutually beneficial
- Importance of building and maintaining trust; industry, regulators, public
- Cloud-based systems are transforming collaborative approaches
- Role of anchor/reference agencies
- Need for intra- and inter-agency advocacy for collaborative approaches
- Need for clear frameworks
- Regional requirements remain challenging

Morning Session – Big Thoughts

- Harmonization
  - Consensus expectations, internal/external harmonization, and processes
  - Better understanding of how we do reliance
- Communication
  - Frequent, transparent, and frank conversations are essential for collaborative approaches
  - Feedback from industry is critical for improving these approaches
  - Challenge function for all parties is critical to help ensure continuous improvement
- Post-approval Changes
  - Consider integrating ICH Q12 within the Access framework
- Could you use a collaborative approach for a product, not just a submission; from authorization through lifecycle?

Afternoon Session – Regulator Discussions

- There is a need for continued and sustained conversations between agencies, including those involving the working-level
- Efforts to harmonize across agencies need both general and submission-specific opportunities for discussions to build the understanding needed to advance harmonization and convergence
- How are agencies looking to strengthen internal harmonization?
- Better and more frequent communication is needed.
- We need to know what we are doing well and what we aren’t doing well
- More feedback and more challenge function

Afternoon Session – Access Discussions

- How do we enable harmonization across the Access partners?
- What would be needed to move to recognition within an Access review?
- Would there be value in forming an Access-QWP or a similar venue to bring reviewers together for discussions that are relevant to CMC review?
- Can we use the Access framework to facilitate training on enhanced approaches as a way to establish convergence at the outset?

Afternoon Session – Outcome

- There is a willingness to engage and to learn from eachother
- Endorsement from leadership will be key to initiating and sustaining the momentum
- Next steps:
  - Targeted sessions on discrete topics: e.g., how we do reliance?
  - Keep the conversation going
  - Internal opportunities to bring efficiences and new ways of working

Thank you