Part 2: A Pandemic Silver Lining?

Optimizing Internal Collaboration Between Medical Affairs, Compliance, Legal, Regulatory and Market Access Roles in a Post-Pandemic MedTech World.

December 9, 2020

Presented by the MAPS MedTech and Compliance Focus Area Work Groups

Disclaimer

The views expressed in this Webinar are those of the presenters and are not an official position statement by their employers, MAPS, nor do they necessarily represent the views of the MAPS members.

This presentation is for informational purposes only and is not intended as legal or regulatory advice.

Moderator

Ann Ford, BSN, JD

Partner

Hall Prangle & Schoonveld, LLC

Objectives

- Review “Lessons Learned” from the Pandemic: How the pandemic has revealed opportunities for the MedTech Industry to support improvements in innovation; communications and engagement; and management of resources and systems.

- Identify key internal and external stakeholders in the MedTech healthcare environment and learn how Medical Affairs professionals can facilitate communications among them.

- Review how the MedTech Industry generally, and through Medical Affairs, may impact the future – what to start doing, stop doing and continue doing.

Housekeeping

Questions for Presenters:

Please submit questions throughout the presentation using the Q&A button in your control panel.

Evaluations:

The control panel includes a webinar evaluation. Please complete that evaluation so that we can work to ensure the highest quality presentations.

On-demand Availability of Webinar:

This webinar, as with all previous ones, will be available on-demand next week in the Community Portal for MAPS members.

Presenters

Philip Desjardins

Vice-President, Global Regulatory Affairs Spine and Medical Device Regulatory Policy

Johnson & Johnson Company

Greg Christopherson

Vice President, Medical Affairs

Medline Industries Inc

David Macarios

Head Health Economics and Outcomes Research, and Payer Engagement

EMD Serono, Inc.

Medical Affairs Role

Can medical affairs help bridge/improve external stakeholder communications

and

assist with restoring and enhancing trust?

Focus Part 2: MedTech Industry Internal Communications and the Role of the Medical Affairs Professional

Pandemic Lessons Learned: Improved internal communication among various stakeholders and the role of medical affairs

Discussion through various key topics that illustrate how the industry can move forward post-pandemic

- Innovation
- Communication and Engagement
- Resources and Systems

Opening Comments:

Regulatory

Medical Affairs

Health Economics

It took COVID-19 less than two months to reduce the volume of elective, semi-elective, and even urgent procedures to unprecedented lows…

With nearly every payer enjoying significant medical cost savings…

For now.

EUA v. Pre-Market Review of Medical Products

EUA

- Declared Emergency Exists
- Product meets reasonable thresholds for safety and effectiveness
- Some evidence that strongly suggests patients have benefited from the product
- Known potential benefits outweigh the known potential risks
- Patients are in urgent need of care

- FDA expects:
- Validation data to be provided for review informally by email at the time of notification
- Any clinical testing completed during the review period should include a statement that the test is validated but that the FDA's review is pending
- Manufacturer makes instructions for use and the performance characteristics available on the its website while it awaits EUA determination

EUA v. Pre-Market Review of Medical Products

Pre-Market Notification

The 510(k) process

- Requires manufacturer to 'notify' FDA 90 days before they propose to begin marketing a new or certain modified device.
- Allows FDA to determine whether a device is substantially equivalent to one or more predicate devices.

Pre-Market Approval (PMA)

- Most stringent type of device marketing application required by FDA.
- Applicant must receive FDA approval of its PMA application prior to marketing the device.
- Approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).

Lessons Learned - Regulatory

US Government Agencies/Regulatory

- COVID impact
  - Increased Flexibility and Focus for FDA and other agencies:
    - Impact on landscape of providers, industry, healthcare regulatory authorities
    - Urgency
  - International/MDR

Role of Government

- Pre-Market – Other than EUA's/FDA?
- Enforcement/Compliance issues

Lessons Learned – Medical Affairs/Clinical research

COVID vs. non-COVID research

- Diagnosis and treatment of COVID – focus
- Other/non-COVID related – slowed or stopped

Data – Medical Affairs Contribution

- Character populations
- Direct research

Communication

Technology

- Pandemic:
  - Forced adoption to some extent
    - Increased user comfort
    - Applicability and utility in global systems

- Post-Pandemic/Long-term
  - Telehealth is here to stay
    - But when all those other activities come on board, where does Telehealth go?

Is Telehealth the solution?

Type of claim	Commercial	Medicaid	Medicare
Overall	–23%	–18%	–15%
Emergency dept.	–16%	–30%	–20%
Hospital inpatient	–4%	–6%	–14%
Office	–29%	–32%	–18%
Telehealth	+7,364	+2,897%	+8.802%

Source: Cotiviti obtained https://www.managedhealthcareexecutive.com/view/how-payers-can-weather-the-covid-19-storm-and-its-aftermath

Engagement among the stakeholders in MedTech

Compliance and Medical Affairs

- Compliance implications of virtual engagements
- Advice for MA professionals for virtual engagements

Health Economics impacts

- US Insurance System Requires Contributions from Various Stakeholders

Regulatory impacts

Regulatory Priorities

Finite regulatory resources require aligned priorities

- Diagnostic
- Secondary treatments
- Vaccines

Pandemic forced focus on top regulatory priorities

- How do we focus on the priorities – COVID impact
  - Example:
    - Pre-COVID – 6 months to go/no-go decision
    - Post-COVID – much shorter
  - Post – COVID
    - This new paradigm does not have to be temporary

- New systems adopted vs. faster adoption of existing systems/processes
  - COVID accelerated an already running train in a very narrow scope around emergency authorizations
    - FDA processes
    - R and D

Health Economics Perspective

Fragile Systems

Accelerated processes – Sustainable?

Hospital and Providers

- Backlog of elective cases
- Elective procedures are not often truly elective (e.g., cancer treatment)

After the Crisis – What are we going to stop, start, and continue?

Health Economics

Regulatory

Medical Affairs

Thank you!

Questions?

Philip Desjardins

Vice-President, Global Regulatory Policy and Intelligence

Johnson & Johnson Company

David Macarios

Head Health Economics and Outcomes Research, and Payer Engagement

EMD Serono, Inc.

Gregory Christopherson

Vice President – Medical Affairs

Medline Industries Inc