KEY ISSUES

➢ EU:
  – Implementation of Medical Device and IVD Regulations
  – Brexit

➢ China:
  – Payment Policies
  – Trade Dispute

➢ India:
  – Indian Government Pricing Policy
  – New Regulatory System

➢ Japan: Reimbursement Revisions

➢ Americas:
  – Brazil Trade Agreement
  – USMCA (NAFTA 2.0)
MDR/IVDR IMPLEMENTATION

**Issues:** Still insufficient Notified Body (NB) Capacity; relief for some Class I

**Actions:**
- Adopted low-key approach for EU Corrigendum to allow until May 2024 for MDR approval for certain Class I
- Continued member updates and joint calls with MTE
- EU advocacy and ensuring Commerce and USTR support
  - AdvaMed/Commerce joint meetings with Member State Embassies
  - MTE meetings with EU Commission, Member States
  - TBT issue raised at WTO, supported by Korea, Japan, Canada
  - Raising specific concerns re: insufficient NB reviews/fees
- Press/Media engagement when asked in coordination with MTE
MDR/IVDR IMPLEMENTATION

Next Steps:

• MTE continued outreach to Commission and Competent Authorities
• AdvaMed supporting MTE messaging with Member States/Embassies
  ➢ Continue to ensure aggressive support by Commerce and USTR leadership, including US Embassies
• Continue engagement with countries impacted by trade restriction
• Coalition building to increase pressure, emphasis on hospitals
• Continue to explore mechanisms to obtain relief/flexibility
• Provide SME and notified body impact examples to Commission
• Seek flexible official implementation guidance from Commission
• Explore EU-wide derogations
BREXIT

**Issues:** Continued Business Uncertainty

**Next Steps:**
- Upcoming Election December 12 should clarify Brexit course
- Two candidates locked into an ‘unpopularity’ contest
- Continue work with MHRA to ensure CE marked products remain on market in UK, and to soften impact from UK NB closings
- Continue work with ABHI and UK Gov’t to ensure UK honors supply chain commitments
- Continue work with MTE to get Commission to ensure flexibility for UK approved products to be sold in EU post-Brexit
- Work with MTE to address re-labeling needs and ensure adequate time
- Continue engagement of concerns with USTR and Commerce
China: Payment Policies

**Issue:** State Council Reform Plan: focus on volume-based procurement (VBP)

**Actions:** Develop advocacy strategy → recognizing severe threat!
- Obtained China Board’s approval on plan to address VBP
- Outreach to USG and European Commission
- China Board provided views on other features of State Council Reform Plan
- Sent Scott letter to China’s Health Minister to seek VBP changes

**Next Steps:** Continue efforts to encourage best-practices
- Comment on tenders to counter inappropriate practices
- Conduct surveys of key VBP tenders for advocacy
- Provide Chinese officials a critique and recommendations about provincial VBP
- Seek meetings with Chinese officials on State Council Reform Plan and VBP
- Monitor State Council Reform Plan to provide recommendations
Issue: “Phase I” of trade negotiations...and beyond?

Key Events
• US-China break off negotiations in May
• Trump increases tariffs
• China-US reach “Phase I” deal on October 11, but still negotiating text
• Trump suspended October 15 tariffs

Next Steps
• US-China conclude “Phase I”?  
• More tariffs removed?  
• Negotiations begin on Phase II?
Tariff Impact on MedTech

**China's Tariffs on U.S. MedTech**
*Nearly all U.S. imports face an additional tariff*

- $4.75 billion (additional tariffs ranging from 5-35%)
- $500 million (no tariff)

**U.S. Tariffs on Chinese MedTech**
*40% of Chinese imports face an additional tariff*

- $1 billion (additional 25% tariff)
- $1 billion (additional 15% tariff)
- $3 billion (no additional tariff)
India: Pricing Policy

**Issue:** Trade talks have picked up and narrow deal more likely

**Actions**
- AdvaMed meeting with Commerce Minister in New Delhi
- Scott and Board Members meet with USTR Ambassador Lighthizer
- Industry coalesces around solution on TMR and pathway for stents and knees
- Scott meets with Commerce Minister in NYC and DC
- November talks following Scott’s meeting yields progress

**Next Steps**
- USTR continues talks in New Delhi
- AdvaMed monitors and encourages progress
- Preparations for reaction to announcement
India: New Regulatory Regime

**Issue:** Growing industry confusion as India pursues competing regulatory initiatives

**Actions**
- With industry support, GOI implements Medical Device Rules 2017
- Industry works towards implementation as Rules comes into effect in 2018
- Summer 2019, speculation grows about new worrisome Act to regulate devices

**Next Steps**
- Analyze pros and cons of possible new act
- Develop white paper which supports current approach and highlights best practices
- Support Health Ministry efforts to roll out Medical Device Rules for all devices
Japan Reimbursement

**Issue:** Reimbursement Rules for April 202 Revision

**Actions:**
- Meetings with Japanese government officials (November)
- Commerce Department high-level visit to Japan (November)
- Congressional letters to Japanese Ambassador (November)
- Industry testimony to Reimbursement Council (November)

**Next Steps:** Continue efforts to encourage best-practices
- Japanese government decision on reimbursement revisions
- U.S.-Japan Trade Agreement – Stage 2
Brazil: Trade Modernization Agreement

**Issue:** AdvaMed advocacy for a U.S.-Brazil "trade arrangement"

**Actions:**
- Advocated with the governments for a new type of trade partnership
- Secured private sector alignment in both countries
- Supported USG and GOB dialogue throughout 2019

**Next Steps:** Increase pressure for accelerated trade talks and deal in 2020
Issue: USMCA requires congressional approval

Actions:
• Supported broad-based coalitions focused on congressional passage
• Major hurdle cleared this week with congressional negotiations
• Medtech negotiating wins remain unaltered
• Passage expected by all three legislatures by Q1 2020

Next Steps: Work with coalitions to push past finish line
THANK YOU!