

TRACK III: Fair Market Value Update

Fair Market Value – The Emerging/Evolving Company

2:15 p.m.

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THE TWELFTH ANNUAL **Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum**

TRANSFORMATIONAL LEARNING –
EFFECTIVE KNOWLEDGE EXCHANGE

The Emerging Company

FMV Analysis Impacts our Entire Business

- Clinical Development
 - Clinical Trial Payments
 - Consulting Payments
 - Protocol Payments
- Medical Affairs
 - Advisory Boards & Other Consulting Payments
 - Publication/Conferences
- Sales & Marketing
 - Advisory Boards & Other Consulting Payments
 - Promotional Speaking
 - Commercial Contracting
 - Service Fee Payments
 - MCO Advisory Board Payments

Challenges in the Emerging Company

- Characteristics of the Emerging Company
 - No commercialized product, but launch approaching
 - Commercial employees are just being hired
 - Existing employees are used to being a part of a research & development focused organization
 - Emphasis on the science, less structured environment
 - Existing employees have not followed what has been going on in the enforcement environment in the past several years
 - Low focus to date, generally, on traditional compliance
 - Missing policies and SOPs related to commercial operations

Challenges/Objections

- “We are so small, we are not on anyone’s radar”
 - Variation: “We don’t even have a product on the market yet, why do we need to be concerned about this?”
- “We have not had compliance (and so many policies) before...is this really necessary?”
- “We are in the R&D organization, surely these rules don’t apply to scientists”
- “Show me where someone has been sued or investigated about this issue?”

HCP Challenges/Objections

- “This is what we have always paid our consultants...they won't take any less”
- “I don't care what the commercial organization wants to pay them for an advisory board, this is what we have always paid”
- “I've worked in R&D at several companies and we have never had to do this before”
- “Why can't we just pay everyone the same amount?”

Tips

- Before trying to implement an FMV policy/analysis, conduct a “Current Environment” training for all employees early on to bring them up to speed
 - Small groups are better as discussion and questions will be more free flowing
 - This can be used to address many of their future objections
- When conducting FMV analysis and implementing a policy, use a cross-functional team that will include representation from all facets of the company
 - This will help ensure that all sides of the business understand what the others are doing
 - Increases buy-in
 - Ensure Senior management is part of the process

Tips

- Be sure your FMV policy has value ranges to allow for flexibility
 - This can help to address concerns regarding different proposed payments to consultants from one part of the organization to another
 - Make sure you have objective criteria when tiering consultants to justify additional value
- Take extra time to address FMV with the R&D organization
 - This represents the most change for R&D
 - Commercial is generally very used to these principles

Questions?

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The Evolving Company

Agenda

- I. The Evolving Company: Building Partnerships And Expanding Into New Geographic Markets
- II. Need To Create Shared Accountability And Governance For FMV Among Partners And Across The Value Chain
- III. Risk Management: Forming the Partnership
- IV. Risk Management: During Execution
- V. The Usual Suspects: Ensuring Alignment And A Process To Govern
- VI. Expanding Into New Geographic Markets: Establishing The Infrastructure

Housekeeping: The opinions expressed herein are my personal opinions and do not necessarily represent the positions of Eisai.


The Evolving Company: Building Partnerships And Expanding Into New Geographic Markets

The competitive pressures facing the industry are accelerating the pace to expand:

- Partnerships
 - Joint Ventures
 - Risk sharing Agreements
 - Co-promotions
 - Use of Contract Sales Organizations
 - Mergers and Acquisitions
 - Product Licensing
- Expansions / Increased investments in new geographic markets

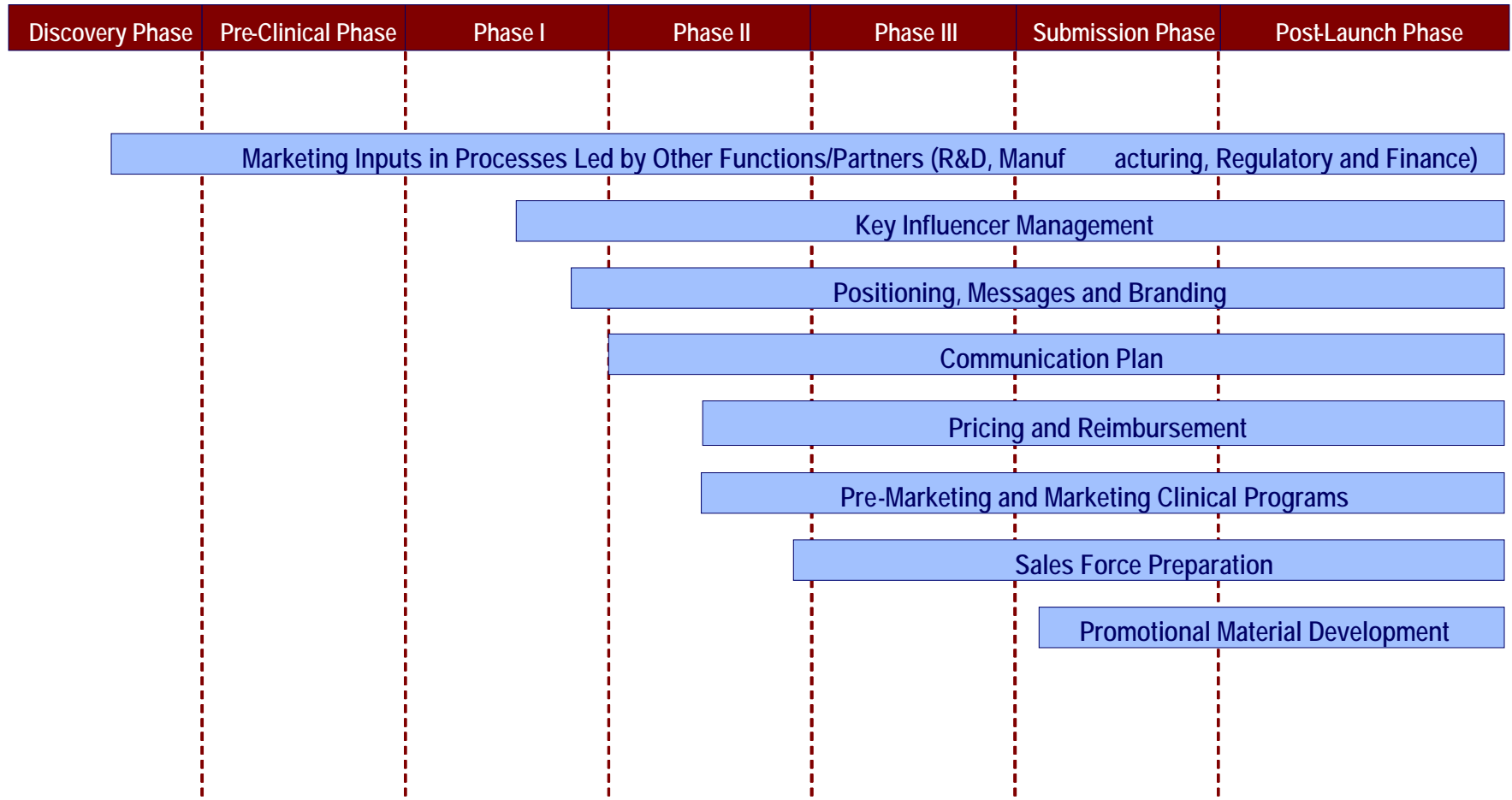
These relationships have high degree of visibility and the emphasis is on performance:

- Primary focus is to establish/increase market presence
- Drive commercial performance in the near-term
- Typically rely on the “traditional” marketing and promotional levers
- ROI driven



Q: How do you ensure FMV Risk is addressed and there is alignment among a variety of stakeholders / different Companies?

Need Shared Accountability And Governance For FMV Among Partners And Across The *Virtual* Value Chain



Alignment, coordination and enterprise-wide FMV governance is needed

Risk Management: Forming The Partnership

- Is Compliance part of the Deal Team?
 - Company Considerations:
 - Do either of the partners have a CIA?
 - Are both Companies signatories of the PhRMA code?
 - Are FMV rates/Policies comparable between the partners?
 - FMV methodology, policy & process
 - Who sets FMV rates for the partnership?
 - Exception process
 - Disagreement on Rates
- Commercial Strategy Alignment
 - Forecasts
 - Approach to the market
 - Brand Strategies
 - Associated promotional activities
 - Funding levels
 - Decision making/Spend
 - Management Teams
 - Tone
 - Compliance environment Understanding
 - Compliance risk tolerance level

Q: Have we embedded FMV intentions and SOPs into the discussions? Is there alignment with regard to FMV?

Risk Management: During Execution

- Alignment on the basics:
 - Who sets FMV rates for the partnership?
 - Who is driving the activity?
 - Is there alignment on the marketing and promotional practices?
 - How will you coordinate FMV for co-promotion activities?
 - Who and what group determines KOL status?
- Monitoring to ensure payments are at FMV
 - What is the process?
 - How do we manage the process in a dual structure and operating environment?
 - Where is the data?
- Training across organization on FMV Process
 - Who will provide training?
 - Is FMV part of the legal review of all contracts?
 - Who will train 3rd party vendors who pay HCPs on company's behalf on FMV process?
- Who is responsible for Sunshine reporting?
- Finally, how do you ensure the FMV process is working effectively and controls are in place to govern activities?

Q: How will FMV be managed on a daily basis - Who? What process?

The Usual Suspects: Ensuring Alignment And A Process To Govern

- Speaker Programs
- Meals & Hospitality
- Educational and Practice-Related Items
- Exhibits
- Sponsorships
- Grants and Charitable Contributions
- Consultant Services
- Market Research



Q: Who will drive these activities and is their alignment on frequency and FMV rates?

Expanding Into New Geographic Markets: Establishing The Infrastructure

- Global Anti-Corruption Laws
 - Foreign Corrupt Practices Act
 - Is there alignment/understanding of the definition of a foreign official?
 - e.g. Depending on the country, many HCPs can be considered a government employee
 - UK Bribery Act
 - There is no exception for a facilitating payment under the act
 - There is broader jurisdictional reach, covering any act committed anywhere in the world by any commercial organization that conducts a business in the UK.
 - Provides increased incentive for companies to have in place an effective anti-corruption compliance program
- What process and documentation will be required that meets company requirements?

Expanding Into New Geographic Markets: Establishing The Infrastructure

- Pre-Partnering Anti-Corruption Due Diligence
 - Background investigation and public database searches of key executives
 - Interviews of key executives related to past corruption and future risks of corruption
 - Review of documents related to partner company's anti-corruption program
 - Auditing procedures related to high risk transaction areas
 - Does the partner have a policy and controls in place to comply with global anti-corruption laws?

- Post-Partnering Risk Mitigation
 - Set tone at the top
 - Translate, distribute and train on anti-corruption policies
 - Adopt a “best in class” compliance program
 - Develop a robust internal audit function
 - Develop a robust monitoring program

Expanding Into New Geographic Markets: Establishing The Infrastructure

- As the Company begins building an infrastructure, what 3rd parties will be used? For what purpose?
- Use of US HCPs
 - Is there agreement that US Regulations and laws follow the HCP
 - Close interaction and coordination to determine appropriate FMV rates for use of US HCPs, including needs assessment
 - Training and guidance on use of U.S. HCPs to foreign affiliates
 - Ensure data is captured for Sunshine Act reported – Who , what process

Questions?

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