Pharmaceutical Regulatory and Compliance Congress

Current Trends in International Fair Market Value
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Agenda

I. Why FMV?
II. FMV Methodology Options & Approaches
III. One Company's Experience
IV. Challenges and Pitfalls of International FMV
V. FMV Implementation Strategies
VI. Q&A
I. WHY FMV?
International FMV: Why create consistent payment methodology?

- Impact on business
  - Exclusion from public contracts
  - Reputational damage
  - Damage to market valuations
  - Loss strategic business opportunities

- Regulators are focused on bribery
- Anti-corruption legislation
  - FCPA
  - UK Bribery Act
- Increased enforcement efforts
  - Corporate Risk
  - Individual Risk
International FMV: Why create consistent payment methodology?

- Establish robust business process to minimize risks of improper influence/corruption
- Proactive approach includes a compliance program that also includes a FMV process for developing, assessing, and supporting FMV compensation of business partners
- Although a proactive approach cannot guarantee there will not be problems, they can greatly mitigate risk and place the Company in a better position to request leniency from the government should a violation occur
- Key processes to developing a proactive approach include:
  - Identifying third-party business partners that may be at higher risk
  - Understanding the Company’s interactions with third-parties
  - Understanding the compensation structure
  - Establish robust process for reviewing business need and justification
  - Establish FMV compensation through a standardized and monitored process
II. FMV METHODOLOGY OPTIONS & APPROACHES
## Fair Market Value Evolution

<table>
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<th>No System</th>
<th>• No particular strategy, approach, or tracking mechanisms</th>
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| Rate Card | • Group similar activities  
            • Payments based on historical payments for similar transactions |
| FMV Process | • Inventory and group transactions  
                  • FMV analysis, models, and tools  
                  • Validate with external data, where available  
                  • Payments tracked and monitored |
| Global FMV Framework | • Multi-national need for governance at global, regional, country, and company levels  
                      • Standardized processes and methods  
                      • Oversight, testing, and monitoring |
Building a FMV Process

- Define FMV and scope of services
- Identify cross-functional team
- Identify and analyze services
- Business justification for services
- Identify data for analysis
- Perform FMV analysis
- Document FMV conclusion
Principles of Fair Market Value

Understanding Basic Valuation Principles

- Currently no specific set of procedures or calculation for setting FMV has been provided by regulatory agencies
- A comprehensive framework should be based on available guidance, as well as established valuation theory
- Valuation theory provides three broad approaches to analysis that relate to the goods or services that are being valued (e.g., cost, income, and market approaches)
- In most cases, one approach tends to emerge as the most appropriate methodology for the valuation analysis
- Other approaches, when feasible, should be used to corroborate analysis
Principles of International Fair Market Value

- Country’s healthcare system and regulations
- Business environment and competitive pressures
- Frequency / speed of market changes in compensation
- Unique market challenges – local country practices
- Nature of activities / services
- Typical structure of agreements and components
- Variability in pay for public vs. private employment
- Variability in pay across specialties
- Variability in pay across regions within the country
- Variability in pay for qualifications / stature / event
Determining Fair Market Value

- How do you determine FMV?
  - Market data – salary surveys, annual compensation, fringe benefits, and pay premiums
  - Hourly compensation – what is the denominator?
  - Level of effort components – prep, travel, and service times?
  - Geographic pay variability – general physician vs. specialty
  - Historical transactions
  - Reference countries

- Cross border arrangements
  - Should rate be based on location of event?
  - Should rate be based on specialty?

- Mix of specialties at same event
  - Should rate be same for everyone?
  - Should rate differ based on specialty?

- Multiple, consecutive events – should rate be reduced for 2nd event?
- KOL stature: regional / national / international
- Event / audience stature: regional / national / international
Developing a Segmentation Strategy

- Developing a segmentation strategy provides the basis for:
  - Identifying and tracking the types of HCP consultants used by the company
  - Managing the types of activities these individuals may be engaged to participant in
- Based upon the underlying specialization of a consultant and his or her expert level, structure should be robust enough to facilitate adding specialists as needed
- Segmenting activities is the basis for determining the appropriate "level of effort" for service and adds transparency to the process
An FMV payment structure should be built upon a segmentation scheme, which considers an HCP’s specialty and expert level, as well as the type of service they are providing for the company.
A robust segmentation strategy will help mitigate risks for overpaying one HCP type vs. another; it will also assist in accurately accounting for the total level of effort associated with a particular activity.
Model for Calculating FMV Payments

- A base hourly rate should be determined by considering:
  - How the HCP’s expert level is addressed (i.e., KOL vs. non-KOL)
  - The compensation levels for the HCP segment

- The total level of effort (“LoE”) for an activity may be determined by considering:
  - The aggregate time spent by the HCP in conducting the activity

- These two elements should comprise the FMV calculation for a specific activity
### Determining Fair Market Value

**Econometric Considerations for the FMV Calculation**

| Use of Established Theories of Competition | In certain circumstances, a market for physician services may not be fully efficient, which results in upward compensation trends for HCPs, such as thought leaders at the forefront of his/her therapeutic area. |


Other Considerations During the Analytical Process

- **KOL Tiering**
  - Use a core set of criteria to determine the expert level of a KOL
  - Use a two- or three-tiered system (i.e., KOL vs. non-KOL, etc.)
  - The same criteria should be used within a division

- **Travel Considerations**
  - The opportunity cost associated with travel time may be different than that associated with service time or preparation time
  - Consider options for travel that include a fixed rate or reduced rate to distinguish from service and preparation time
Considerations for Exceptions

- Develop formal evaluation criteria to determine whether a physician’s expertise warrants an exception.
- Criteria should be focused on demonstrating the physician’s uniqueness and potential demand:
  - Consider the "level of effort" and the underlying replacement value of that individual.
- Implement defined approval matrix and documentation requirements for exceptions supporting a consistent process.
Key Take Aways

- Global FMV framework – standardized process
  - Ensures consistency for governance
  - Enhanced efficiencies – data gathering and supporting documentation
  - Easier to test and monitor
  - Easier to update
- Define FMV and scope
- Determine company involvement and outside consultants
- Get key stakeholders involved and keep them involved
  - Business strategy
  - Finance and contract management
  - Compliance
  - Legal advisors
  - Valuation advisors
  - Others?
- Pilot study – test FMV methodology
- Education and training
III. ONE COMPANY'S EXPERIENCE
**Medical Expert (ME) Management – Why go here?**

- Lack of a standardized process across the BU led to:
  - **Inconsistent interactions** with MEs,
  - **Lack of transparency** regarding relationships/communication, and
  - **Inconsistent financial payments**.
- These deficiencies can cause following risks:
  - Legal,
  - Compliance,
  - Reputational, and
  - Suboptimal commercial utilization.
- Several, recent interactions were noted as the driver for this project.

**What did we do?**

- We looked to solve the problem across 4 areas; considering as scope all international speaking/consulting arrangement with HCPs across commercial/medical:

1. **Consistent definition / scope**
   - Common definition and criteria across Oncology of an international/global KOL

2. **Interaction processes**
   - Clear & simple process to interact with those we define as a global/international KOL
   - Compliance to local laws

3. **Financial payments**
   - Consistent honoraria across regions/functions
   - Clear agreement on travel/board

4. **Aggregate usage**
   - Tracking and/or caps on usage of KOLs as Novartis Oncology
NVS Lessons Learned

- Many countries have an informal or unvalidated “FMV” number, which is currently used.
- Nobody wants to change current practices.
  - All agree on the need; nobody agrees on how to solve.
  - View that FMV methodology is too complicated.
- Experience akin to “herding cats”.
  - Developing FMV was easy compared to gaining agreement.
- Never underestimate the need for broad stakeholder management commitment.
  - And time it takes to get it!
IV. CHALLENGES AND PITFALLS OF INTERNATIONAL FMV
International FMV Challenges

- Availability of external data
- FMV expertise
- Frequency / speed of market changes
- Industry / stakeholder involvement
- Domestic company competitive advantages
- Industry association restrictions
V. FMV IMPLEMENTATION STRATEGIES
Implementing an FMV Strategy

Considerations for Implementing a New FMV Process

- Include stakeholders during the analytical process, which will facilitate buy-in and understanding for a new FMV rate structure and process
  - Those who identify and hire HCP consultants
  - Those who calculate and determine payments to HCPs
- FMV payment structures should consider operational and business needs
  - Contracting requirements
  - Communication of assumptions to facilitate any discussions with contracted HCPs and other business partners
- Preserve as much consistency with current process, as much as possible (i.e., submission of contracts, approval matrix, etc.)
Implementing an FMV Strategy

Challenges to Implementing a New FMV Process

- Differing compensation arrangements that may exist with HCPs across several functional areas within each business unit
  - Does the company have defined criteria for defining KOLs?
  - How does a physician’s KOL status vary across divisions?
- Differences from historical honoraria rates
- Varying degrees of technical skill for end-users; a technology platform should reflect the skill set of FMV end-users
- Efficient support system to address ad hoc questions from to support users
Question & Answers?