



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?*

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- Regulators are focused on bribery
 - Anti-corruption legislation
 - FCPA
 - UK Bribery Act
 - Increased enforcement efforts
 - Corporate Risk
 - Individual Risk
 - Impact on business
 - Exclusion from public contracts
 - Reputational damage
 - Damage to market valuations
 - Loss strategic business opportunities

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

No
System



- No particular strategy, approach, or tracking mechanisms

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

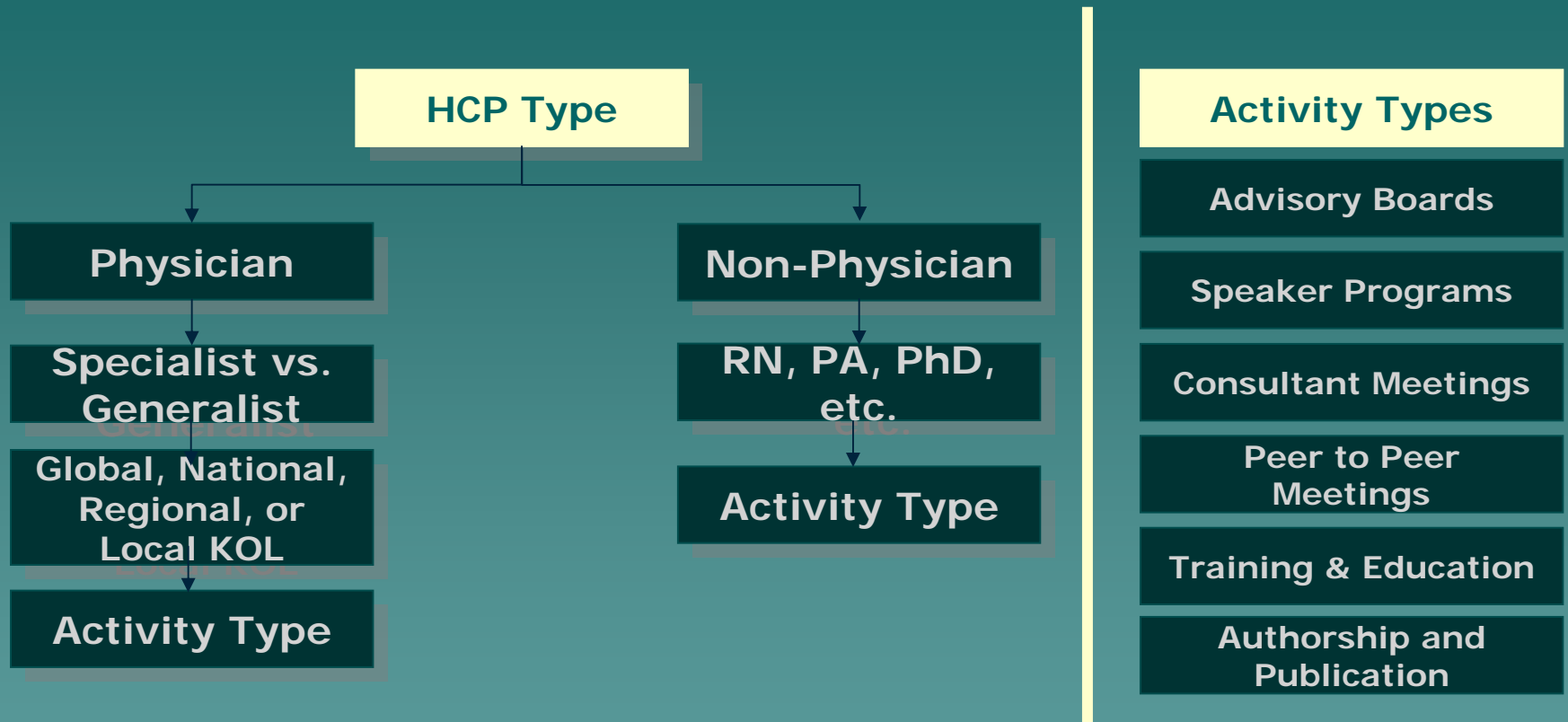
Determining Fair Market Value

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 participate 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

Determining Fair Market Value

Example Segmentation Scheme



- ◆ 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

Determining Fair Market Value

Example Segmentation Scheme

Sample MD Segmentation Strategy:

- ❑ **Segment I**
 - General Practitioners
 - Family Practitioners
 - Pediatricians
- ❑ **Segment II**
 - Cardiology
 - Neurology
 - Gastroenterology
- ❑ **Segment III**
 - Surgical Subspecialties
 - Oncologists

Alignment of Service Areas:

- ❑ **Key Service Areas:**
 - Physician Training
 - Advisory Boards
 - Product Development
 - Sales/Employee Training
 - Training Material Development
 - Marketing Activities (white papers, physician materials)
 - Research/Publication Services

- ◆ 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

Determining Fair Market Value

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.

Determining Fair Market Value

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

Determining Fair Market Value

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

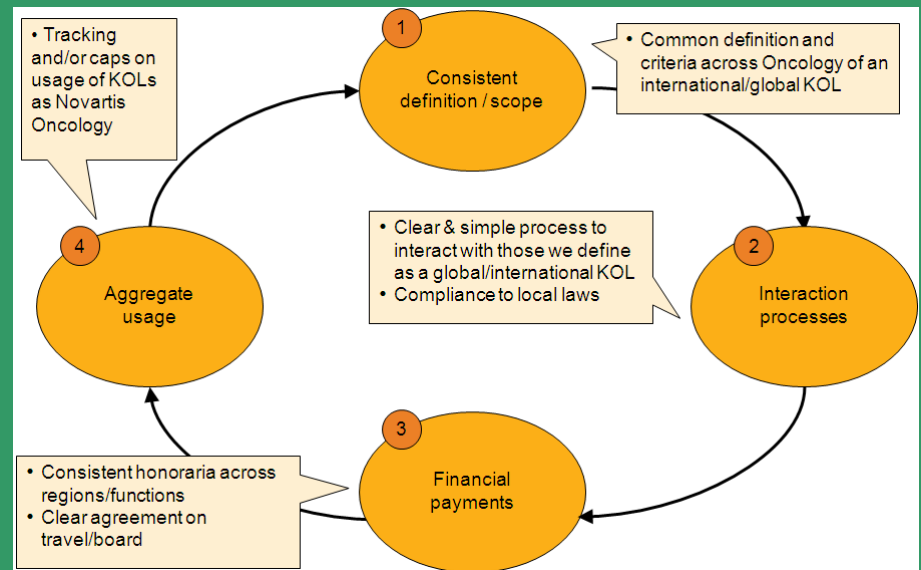
Novartis Oncology: Initiative Overview

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:



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 support users

Question & Answers?

