FMV Framework and Calculation
Best practices in an evolving regulatory environment

16 Nov 16  |  Geert van Gansewinkel
Agenda

Fair market value: why relevant?

Framework and methodology

Implementation best practices

Q&A
What is Fair Market Value and why is it relevant?

The concept of Fair Market Value is broad…
- “A price at which buyers and sellers with a reasonable knowledge of pertinent facts and not acting under any compulsion are willing to do business” (Merriam-Webster)
- “Payments for research services should be Fair Market Value for legitimate, reasonable, and necessary services.” (OIG’s Compliance Program Guidance for Pharmaceutical Manufacturers)
- “The compensation for the services must be reasonable and reflect the Fair Market Value of the services provided” (International Federation of Pharmaceutical Manufacturers & Associations (IFPMA))
- “Any remuneration must be reasonable and reflect the Fair Market Value of the work” (ABPI)

… And has different impact

FMV analysis & engagement ensures Commercially reasonable & viable business decisions

Compliance
The development of systematic anti-corruption laws enhances the importance of FMV

North America
- USA Foreign Corrupt Practices Act (1977)

South America
- Colombian Anti-corruption Act (2011)

Europe
- UK Bribery Act (2010)
- German Act on Fighting Corruption in the Healthcare Sector (2016)
- France Sapin 2 (2016)

APAC
- UAE Penal Code (1987)

Africa
Transparency requirements lead to higher scrutiny of HCP engagements – information more easily accessible

**North America**
- USA (Federal and State laws)
- Canada (upcoming code)
- Mexico (upcoming)

**Europe**
- EFPIA
- Local laws and regulations
- Medtech (upcoming)
- Generic (upcoming)

**APAC**
- Japan (code)
- Australia (code)
- Saudi Arabia (upcoming)

**South America**
- Colombia (upcoming)

**Africa**
- No report currently
Setting fair market value for HCP engagements should address three broad categories of challenges

- Methodology should be robust and consistent, yet flexible
- Methodology should be valid for cross border, i.e. globally
- Implementation should be practical

Implementing global FMV methodology is challenging
Methodology development and application needs to balance consistency with country-level flexibility

- Basic principles of FMV methodology need to be consistent across global affiliates:
  - Need to establish common standards on key methodology components (i.e. rate development, HCP tiering criteria)
  - Differentiation between nomination and tiering of HCPs
  - Use of common guidelines to ensure consistency of fees for similar services

- Methodology needs to also account for local market differences or industry code guidance as this relates to:
  - Differences between countries with predominantly public vs. private/mixed healthcare markets
  - Rate determination more challenging due to lack of robust data in emerging markets
  - Compensation caps, types of activities for which compensation is permissible, flexibility around compensation for travel time, compensation by specialty vs. using single rate
Increased frequency of cross-border HCP engagement necessitates effective governance at multiple levels

Cross-border engagements

• Difficult to standardize planning and budgeting as well as HCP nomination process for cross-border activities
  o Local affiliates may use disparate criteria for selecting HCPs for participation
  o Spend capture for cross-border activities may not be in local country spend disclosure

• Consistent approach for compensating HCPs at cross-border engagements can also be challenging
  o Business goal to compensate all HCPs the same at such activities often made difficult by differences in underlining FMV rates base on country of practice
  o HCP may have different FMV for local versus cross-border engagements

• Lack of visibility between local-level and global compliance organizations can present a challenge
Implementing new FMV rates and processes poses challenges related to adoption and buy in

• Significant challenge in adopting a global FMV approach while at the same time ensuring there is sufficient buy in at the local level
  o Effective training needed at the local level
  o Cross-functional involvement needed
  o Rate implementation at the local level needs to be driven by local business and compliance teams
  o Commitment of local business leadership and of designated “Champions” needed
  o Process automation needs to balance global standardization with local implementation needs

• Defined management of exceptions

• Maintaining FMV based on country-specific macroeconomic conditions
  o For example, HCP FMV rates in politically and economically less stable countries will require more frequent updates than rates in more stable markets
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Best practice Fair Market Value methodology is based on four key principles

1. **Pay market rate for consultant’s time, not for the value of the service**
   Since paying for time, rates should not vary based on type of service

2. **Assure methodology supports higher fees for higher expertise**
   Required to pay “Thought Leader” higher fees

3. **Create an effective process for evaluating physician expertise and determining “Thought Leader” status (i.e. Local, Regional, National, etc.)**
   Required to avoid kickback allegations

4. **Ensure all elements of the fee determination are grounded on objective and transparent data analysis**

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FMV methodology designed to be:

*Flexible, Consistent, Objective and Auditable*
An effective FMV methodology is typically based on 3 key components

FMV Rates

Tiering Model

Activity Fees

Fair Market Value Compensation

While FMV rates based on objective data are a key control in the HCP engagement process they need to be supported by robust tiering models and consistent activity fee practice

- Compensation data used for FMV represents national averages
  - Industry not routinely engage “average” physicians

If you compensate based on tier, without a standard methodology it is difficult to ensure consistency

- If you lack consistency, the control is not working
- Depending on your rate methodology the overpayment could be 20% - 80% depending on country and specialty

FMV as a risk control is also strengthened if companies pay similar fees for similar activities based on standard service level expectations
FMV hourly rate calculations should be based on an objective assessment of total HCP income

1. Analysis of Salary Data

2. Adjustment for Non-Cash Compensation (such as health benefits)

3. Calculation of Hourly Rates

4. Adjustment to Consulting Service Rates

5. Calculation of KOL Premiums*

*KOL Premium determination will leverage a number of factors including private sector compensation, level of seniority at government hospitals and tenured positions at universities

Base FMV Hourly Rates
(i.e. For Tier 3 Physicians)

Tier 1 & Tier 2 FMV Hourly Rates
Multiple sources of information are available to address challenges of data availability

<table>
<thead>
<tr>
<th>1. Physician income data</th>
<th>2. PPP labor indexed</th>
<th>3. GDP per capita indexed</th>
</tr>
</thead>
<tbody>
<tr>
<td>In majority of markets, FMV determined on the basis of physician income data</td>
<td>FMV fees can also be estimated by using purchasing power parity labor indices</td>
<td>FMV fees can also be estimated by modeling the relationship of Physician Incomes to GDP per capita</td>
</tr>
<tr>
<td>Physician income data is available for majority of markets in North America, Europe and Latin America as well as some markets in Asia and the Middle East</td>
<td>Salaries in several countries will separately be indexed to the target country to develop a composite FMV estimate</td>
<td>This approach is used to augment the PPP Labor Indexed estimate</td>
</tr>
<tr>
<td>Data can also be supplemented by using information provided by international organizations such as OECD and the European Commission</td>
<td>It can also be appropriate when aggregating to regional rates (for example for The Caribbean or Gulf countries regions)</td>
<td>For countries where a PPP Labor Index is not available, this approach can provide a basic rationale for determining FMV</td>
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</table>
In addition to FMV hourly rates, fees can be set at activity level

**Base Rates**

- Base rates based on physician income as well as other types of benchmarking data
- Adjust and standardize data using external labor market research
- Calculate hourly base rate for consulting services

**Rate Implementation**

- Build an Activity-Based Cost model by program type (speaker program, advisory boards etc.)
- Validate premium ranges
- Identify appropriate contracting fees based on activity assumptions

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**Fair market value methodology components**

Illustrative

<table>
<thead>
<tr>
<th>EUR</th>
<th>Hourly base rate</th>
<th>KOL</th>
<th>Event</th>
<th>Travel</th>
<th>Role/prep</th>
<th>Total fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>500</td>
<td>1,000</td>
<td>1,500</td>
<td>0</td>
</tr>
</tbody>
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Wage survey

Activity model (hours)
KOL premiums should be based on an objective assessment of HCP expertise

Categories of Expertise

- Employment
- Publications & Trials
- Speaking & Advisory
- Associations & Journals

Tiering for KOLs

- Tier 1
- Tier 2
- Tier 3

Scoring Model for Expert Status - example

Exceptions:
- Determined based on facts and circumstances

Tier 1:
- Top expert in a country
- Requirement: Scored Tier 1 in at least 2 of 4 categories

Tier 2:
- Significantly above average expertise, broadly recognized by peers
- Requirement: Scored Tier 2 or higher in at least 2 of 4 categories

Tier 3:
- Average to above average expertise
There should be a difference between selection and tiering criteria

<table>
<thead>
<tr>
<th>Selection criteria</th>
<th>Tiering criteria</th>
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<td>Previous experience in working with the individual</td>
<td>Years of employment and employment status</td>
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<tr>
<td>Familiarity of the individual with the product</td>
<td>Level of expertise within the field</td>
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<tr>
<td>Ability to influence</td>
<td>Expert publications in recognized media</td>
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<tr>
<td>Speaking/presentation skills</td>
<td>Involvement in recognized advisory boards</td>
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<tr>
<td>Public profile</td>
<td>Peer reputation</td>
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Selection criteria can drive whether or not to want to work with an individual, but should not drive the setting of Fair Market Value

Tiering score will drive KOL tiering status and therefore FMV rate
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A robust implementation strategy is critical to ensuring a high level of buy-in from all stakeholders

Establishing consistent FMV methodology practices with the input of global/regional leadership is critical to successful FMV program implementation

- Methodology development needs to address key enterprise principles

Initial training and roll out should be designed to empower local stakeholders to own FMV process

Process automation will also enable the consistent application of the FMV methodology

Ongoing local ownership through “FMV Champions” also seen as a best practice in ensuring organizational buy in
Typical considerations to be addressed to ensure stakeholder buy-in during implementation

**Methodology considerations**

- How should KOL status be determined?
- How should travel be compensated?
- Should there be daily or annual payment limits?
- How should same day speaking engagements be handled? (only travel once)
- Should physicians with different specialties be compensated differently at the same consulting event (e.g. advisory board)?
- How should exception processes be managed?

**Change management considerations**

- How should low/high fee outliers be dealt with?
- How to handle structural over-payment in the market?
- What are the implementation considerations when HCP specialties are misaligned to country FMV?
- What are best practices for rate realignment minimizing business impact?
- Should recommended fee be a range or a number?
- What should be addressed in an implementation plan?
- How should model base rates be updated in years to come?
Potential approach to global buy: design, pilot, roll out

**Design**

- Ensure core team is constructed carefully: central experts, and involvement of local (potential) champions
- Design methodology and key drivers centrally with core team
- Take potential local considerations in mind from the start

**Pilot and roll out**

- Pilot test methodology for one of two carefully selected markets
  - Important, yet not so different that others will say “this will not apply here”
  - Geographically well selected (e.g. try not to use UK if HQ is in UK)
- Incorporate findings of pilot test into model, refine methodology
- Roll out to all markets, using selected local champions
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