

<b>CSL™</b>	Intercontinental ComOps Fair Market Value (FMV) Guidelines for Fee-For-Service engagements with Health Care Professionals	
	Doc #: ICO-SOP-MAF-01	Version: 2.0
	Effective Date: October 1 <sup>st</sup> 2018	Supersedes: 1.3

**Applicable to:** This Guideline applies to Intercontinental Commercial Operations (ICO)

**Refers to:** GMA-GDL-FMV: GUIDELINE: Fair Market Value in ComDev  
 COMPASS Global Operating Guidelines - October 2015.  
 ICO-SOP-MAF-01 - Appendix 1 - ICO WPD\_Consultant request form  
 ICO-SOP-MAF-01 - Appendix 2 - FMV worksheet  
 IFPMA Code of Practice (2012)

**Revision Interval:** 3 years

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**Distribution to the following functions within ICO Region (Regional and Country level):**

- General Managers & Country Mangers
- Marketing and Sales
- Medical Affairs and MSLs
- Market Access
- Legal Affairs
- Business Integrity (Compliance)


Intercontinental ComOps Fair Market Value (FMV) Guidelines vs. 2.0

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Version History			
Date	Version	Summary of Change	Author
March 2 <sup>nd</sup> 2016	1.0	Created	Gunnar Philipp
May 2 <sup>nd</sup> 2016	1.1	Editorial changes	Gunnar Philipp
May 16 <sup>th</sup> 2017	1.2	Conversion in new template. Adaption to Global FMV guideline (GMA-GDL-FMV) effective since April 2017.	Gunnar Philipp
October 1 <sup>st</sup> 2018	2.0	Major revision of Chapters 4, 5, 6 updated. <ul style="list-style-type: none"> <li>○ All FMV calculated based on hourly rates.</li> <li>○ KOL tiering aligned with COMPASS</li> <li>○ Simplified FMV calculation process with Excel template</li> </ul>	Gunnar Philipp

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## 1. Purpose

The purpose of this document is to establish the concept and process for determining the amount of honorarium or remuneration to be paid to healthcare professionals (HCPs) practicing within the territory of Intercontinental ComOps for fee-for-service engagements (e.g., advisory boards, investigator meetings, speaker and/or chair services and any other fee-for-service engagements). This applies to healthcare professionals residing in a country in the responsibility of Intercontinental ComOps regardless of the country where the services are provided.


## 2. Audience and Scope

CSL Behring Intercontinental Commercial Operations (ICO) conducts interactions with HCPs in a highly professional, ethical and transparent manner. Engagement of a HCP to provide a service to CSL Behring must be based on legitimate business or scientific need that is documented in advance. These interactions may not be used to reward or influence HCPs to use, prescribe, purchase, recommend, approve or reimburse any product or service, gain access to competitor information or to influence a HCP's technical or regulatory position. The criteria for selecting a particular HCP should be directly related to the identified purpose and the number of HCPs selected as consultants should reasonably reflect CSL Behring's business or scientific need.

For any fee-for-service engagement CSL Behring will pay the HCPs no more than a fair market value (FMV) for their services. All CSL Behring employees who engage HCPs for Fee-For-Service are required to follow this process to determine the appropriate compensation for the engagement of HCPs residing in a country of ICO.

This process applies to HCPs engaged by CSL Behring, either directly or through a third-party vendor, as speakers/chairs, consultants, advisors or investigators, who must be selected based on their current academic and clinical qualifications, experience and expertise. If the HCP is a government official as defined in section 3 of this SOP, CSL Behring's Business Integrity (Compliance)/legal department must be consulted before any consulting discussions take place to assess any potential conflict of interest.

Affiliates in ICO can develop and implement local processes for the management of FMV as long as they are compliant with requirements outlined in this regional SOP (ICO-SOP-MAF-01) document. If a valid local/national FMV process is in place in an affiliate, the local FMV process is applied to HCPs in the respective country instead of this regional SOP. If no local process is deemed to be required, this regional SOP must apply.

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### 3. Terms and Definitions

Term	Definition
Advisory Board/Consultant Meeting	CSL BEHRING can enter into an Advisory Board Agreement if the specific HCP's contribution is objectively justified and needed to obtain expert's advice on the development of medical or marketing activities relating to a CSL BEHRING product or other needed advice. As a result, the sole objective of Advisory Boards is to obtain advice and they must not be used as tactics or business opportunities or forums to provide information. Examples include pre-clinical discovery programs, product development plans, clinical trial protocols, research programs and marketing programs.
Fair Market Value (FMV)	Price of a service between a willing buyer and a willing seller, neither being under any compulsion to buy or sell and both having reasonable knowledge of the relevant facts. The determination of the FMV of services is based on the type of service provided; the time spent providing the service and the HCP's academic and clinical qualifications, experience, expertise and scientific/clinical influence in the scientific community. FMV fees must reflect a legitimate business relationship that provides identifiable service to the company and must not be based or regarded as an opportunity to influence or reward HCPs.
Fee-For-Service (FFS)	Activities related to the delivering of services by HCPs to CSL BEHRING, in the context of a fee for service agreement and based on a legitimate business and /or scientific need and through a payment based on fair market value (e.g., Advisory Boards, Speaker Training, Investigators Meetings, etc.). The agreed period for services may not exceed two-year period.
GM / CM	General Manager / Country Manager
Government official	For the purpose of this SOP, the term "government official" describes: <ul style="list-style-type: none"> <li>- An employee or officer of a governmental ministry, agency, commission, or public national or international organization</li> <li>- A holder of public office, candidate for public office, political party, official of a political party or member of a royal family</li> <li>- An immediate family member of any of the foregoing</li> </ul>



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Healthcare Professional (HCP)	<p>“Healthcare professional” means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product (IFPMA Code).</p> <p>National definitions of the term HCP, e.g. based on local industry codes and legislations, may deviate or be more specific and must be taken into account as well.</p> <p>For the determination of Fair Market Value to other stakeholders (e.g. payers) this process is not applicable. Please refer to the applicable process or reach out to Business Integrity (Compliance) function if in doubt.</p>
Project initiator	Person who signs and submits the speaker request form (Appendix 1 to this SOP)
Symposium	A company-organized educational program at which scientific or disease-state information is provided to HCPs. A symposium may be held in association with a medical society meeting or independently and are governed by local promotional regulations.
TA	Therapeutic Area

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#### 4. Responsibilities

Person/ function	Responsibilities
Project initiator	<ul style="list-style-type: none"> <li>Identify and document legitimate business need for contracting an external expert.</li> <li>Identify the HCP for Fee-For-Service engagement</li> <li>Populate and submit Fee-For-Service engagement request form (Appendix 1) to Medical Affairs function.</li> <li>File Fair Market Value related documentation and keep it available for audits and inspections</li> </ul>
Medical Affairs Reviewer (or deputy)	<ul style="list-style-type: none"> <li>Review Fee-For-Service engagement request form (Appendix 1)</li> <li>Calculate / approve Fair Market Value based on FMV Worksheet (Appendix 2)</li> </ul>
General Manager / Country Manager  And Medical country function	<ul style="list-style-type: none"> <li>Keep oversight on local requirements on Fair Market Value (FMV) e.g. in Pharmaceutical Codes, national laws, regulations etc.</li> <li>Informs of any country external regulation developments with regards to FMV to ICO Medical and Business Integrity (Compliance) functions.</li> <li>Initiate implementation of a local/national Fair Market Value Process if this is needed to ensure compliance with local FMV requirements.</li> </ul>
Managers of distributor contracts	<ul style="list-style-type: none"> <li>Ensure that the respective contracts with 3<sup>rd</sup> parties / distributors addresses the roles and responsibilities outlined in this SOP</li> </ul>

#### 5. Process for HCP Identification and Selection

Once a legitimate business or scientific need has been agreed and documented by the project initiator in the consultant request form (appendix 1), potential HCPs for a Fee-For-Service engagement may be identified and selected. The project initiator is the process owner and responsible for preparing and collecting approvals, proper implementation and keeping documentation of the FMV process for any monitoring and/or audit reviews. The selection of a HCP is based on a HCP's general medical expertise, reputation, knowledge and experience in a particular therapeutic area and the legitimate business and/or scientific need identified. A qualified HCP can be selected based on CSL Behring's customer relation management tool (COMPASS), if the respective Expert has been profiled in this system and a KOL level has been defined as outlined in chapter 6.4. of this SOP.




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In case a new HCP expert is selected who has not been profiled in COMPASS yet, the most recent curriculum vitae (CV) should be available showing evidence of appropriate education, training and experience in the therapy area for which he/she will be providing services to CSL Behring.

HCP are engaged using the following process. The responsibility for completing all steps, providing the necessary supporting documentation, and obtaining approvals sits with the project owner. This process ensures full transparency.

<b>Working step</b>	<b>Responsible</b>
1. Identify a legitimate business and/or scientific need and file documentation	Project Initiator
2. Identify HCP consultant (with consultation of medical affairs if needed)	Project Initiator
3. Complete the CSL Behring Fee-For-Service engagement request form (Appendix 1)	Project Initiator
4. Submit to the respective Medical Affairs person for review <ul style="list-style-type: none"> <li>- Request Form (Appendix 1)</li> <li>- Agenda of the meeting</li> <li>- CV of the HCP (if new expert)</li> </ul>	Project Initiator
5. Conduct Fair Market Value assessment using the Fair Market Value Worksheet (Appendix 2)	Medical Affairs Manager delegate (Affiliate or regional)
6. Approve and sign Request Form (Appendix 1) and Fair Market Value Worksheet (Appendix 2)	General Manager / Country Manager (for affiliates) or Sr. Director Marketing & Medical Affairs (for regional projects)
7. Request the generation of a fee-for-service engagement Agreement by the Legal Department	Project Initiator / Legal Affairs
8. Align agreement with HCP	Project Initiator
9. Obtain appropriate internal, HCP, and HCP employer (where applicable) signatures on the two original or e-signed, as applicable (see Companion country matrix) contracts.	Project Initiator / HCP
10. Send one original, if any, signed copy to the supporting Legal Department; the other to the HCP.	Project Initiator
11. Retain copies with the project documentation for any monitoring and/or audit reviews etc.	Project Initiator

Note: All completed, signed forms and supporting documentation should be retained by the Project Initiator in order to be easily retrieved as needed during any monitoring and/or audit reviews.

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In order to be reimbursed for completed services, the HCP must forward an invoice plus original receipts to the project initiator, who will review and confirm that the payment should be made. The invoice and accompanying receipts should then be forwarded to the appropriate Accounts Payable Department.

All documentation, including a copy of the signed contract, the HCP's CV, supporting credentials, the FMV determination, and any specific training records for HCP (whenever applicable) must be retained. These need to be easily retrieved, consistent with the Global Records Retention Policy.

## 6. Instructions for the Fair Market Value Process

### 6.1. HCPs from Countries ex ICO

Fee-For-Service engagements with HCPs residing and practicing in other regions, i.e. ComOps Europe, ComOps North America, ComOps Asia Pacific, is allowed. However, the Fair Market Value determination is conducted by the responsible Medical Affairs Department of the country of residence of the selected HCP.

#### IMPORTANT:


Never contact HCP from other Countries without proper notification to the responsible Affiliate / Region, since their specific regulations, laws and internal SOPs must be complied with. This also applies to HCPs attending an activity/event (i.e. not engaged in Fee-For-Service engagement). The Fair Market Value must be calculated based on the local FMV process valid in the respective country/region where the requested HPC practices.

### 6.2. HCPs from Countries in ICO

For countries within ICO with a legal entity in place (affiliate, branch office etc.) the GM or CM along with country Medical Affairs function must ensure that a valid local FMV process or a local appendix to this SOP with local FMV hourly rates is in place reflecting all local requirements including but not limited to those defined in the applicable pharma codes, local laws and other regulations. Affiliates must share this local SOP or attachment with the Director Medical Affairs ICO for information within 6 months after the regional SOP becomes effective.

For countries managed by CSL Behring via a 3rd party service provider (e.g. an agent or distributor), the 3rd party service provider must inform CSL Behring about all Fee-For-Service activities with HCPs and obtain approval from the responsible CSLB GM or CM and Medical Affairs representative for the respective country before entering any legally binding



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commitments or obligations. The CSL Behring contract manager is responsible to ensure 3rd party distributors are informed and follow these requirements in an appropriate way.

For HCPs residing in countries in ICO without a local FMV process in place this SOP ICO-SOP-MAF-01 is applicable and must be followed.

### **6.3. Required Documents for Consultant Requests**

The project initiator is responsible for submitting a complete set of documents required for the Fair Market Value Review, these include

- The HCP Consultant Request Form (Appendix 1)
- An Agenda of the Meeting where the services will be provided to justify the scope of work.


The agenda should include all the relevant information such as the location where services are required, day and time of the event, title of the event, title of the speaker's presentation, duration of the speaker/chair services, organizer (if applicable), etc..

The Project initiator submits these documents to the Medical Affairs Reviewer for FMV calculation.

### **6.4. KOL Level Rating**

CSL Behring has defined guidelines in place how to rate the level of a Key Opinion Leader (COMPASS Operating Guidelines). External Experts / Key Opinion Leaders are profiled based on specific criteria, such as:

- Number of published works
- Number of cited publications
- Membership in Medical Associations/Societies
- Appointed academic positions
- Participation in Editorial Review Boards for Scientific Journals
- Lectures at Associations and Scientific Meetings
- Authorship / Contribution to textbooks

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The following levels of KOLs shown in the table below are defined and reflected in COMPASS, the Customer Relationship Management System used in CSL Behring.

Level	Compass classification	Explanation / Responsibilities
Global Scientific expert	Global KOL	Global KOLs are the responsibility of the Head of Commercial Development or delegate.
Regional Scientific expert	Regional KOL	Regional KOLs are the responsibility of the Regional General Manager or delegate.
Local Scientific expert	Local KOL	National KOLs are the responsibility of the Country General Manager or delegate.
other	No KOL	n.a.

## 6.5. Fair Market Value Calculation

Medical Affairs determines the Fair Market Value using the Intercontinental FMV Worksheet (Appendix 2).


The Medical Affairs reviewer also verifies the submitted information for completeness, consistency and accuracy. This includes that information on the HCP (KOL level, country of residency) must be consistent with the profile in COMPASS.

All FMV calculations in this process are based on hourly rates specified in the intercontinental FMV Worksheet. Therefore, the scope of work as well as the number of hours of work expected are essential. Approvers are responsible to check if the hours are plausible and consistent with the submitted agenda.

The Intercontinental FMV Worksheet must be signed by the Medical Affairs Reviewer and a second approver (4 eyes principle). Once the FMV Worksheet is completed and signed it is returned to the Project initiator.

## 6.6. Exceptions to the Fair Market Value

In rare cases, exceptions to the pre-approved rate schedules may apply. This may apply to a unique physician who is having a unique set of expertise/knowledge and clinical exposure in a specific TAE. Exceptions should be very limited in number and limited to specific, pre-defined situations and rigorously documented.

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Any such exception will only be considered where truly unique, highly technical or specialized advice /knowledge is required. Approval of the exception will be evaluated based on:

- The rationale and nature of the advice/knowledge required
- The unique qualifications, credentials, and/or technical expertise of the HCP as it relates to the stated objectives of the engagement
- The reasonableness of the fee as it relates to these criteria and the current economic and market conditions

Any proposed payment to an HCP that exceeds the established contracting schedule must be approved in advance of the engagement by all of the following reviewers:

- Dir Medical Affairs Intercontinental
- Dir Business Integrity (Compliance) or legal department

If an exception is approved, the nature and reasons should be entered onto the KOL Fair Market Value Assessment Worksheet in the appropriate section.

## 6.7. Final approval

The Fee-For-Service engagement Request Form (Appendix 1) must be signed for final approval. Final approvers are the General Manager or Country Manager (for affiliate projects) or the Sr. Director Marketing, Medical Affairs, Market Access (for regional projects).

### **Please note:**

FMV calculations represent the **maximum** remuneration rate for a KOL and should be used as an upper limit. FMV may be adjusted downwards based on current CSL Behring policies and practice, as well as history with that KOL or within the particular therapy area.

## 7. Appendices

[Appendix 1: HCP Consultant Request Form](#)

[Appendix 2: Intercontinental Fair Market Value Worksheet](#)