HCP Services

Scope of application: Bayer China Pharmaceuticals Division (incl. Radiology) and Consumer Health Division
Regulation No.: Compliance-010-V2.0
Effective: April 3, 2017

Document Attributes

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Replaces:	HCP Service Directive BHC Regulation No.: Compliance-010-V1.0

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1 General Provisions

1.1 Objective

Bayer China may contract HCPs to provide scientific services in accordance with relevant business need. This Directive is intended to provide guidance on the types of services, qualifications of HCPs, remuneration and other topics to be considered in this respect.

1.2 Scope

This directive applies to all employees of Bayer China Pharmaceuticals (including Radiology) and Consumer Health.

It shall comprise the operations of below Legal Entities:

- [LE0882]_Bayer Healthcare Company Ltd (hereinafter referred to as “BHCL”)
- [LE1757]_MEDRAD Medical Equipment Trading Company-Beijing (hereinafter referred to as “MMET”)
- [LE1953]_ Bayer Healthcare (Shanghai) Company Ltd. (hereinafter referred to as “BHSC”)
- [LE1954]_Dihon Pharmaceutical Group Company Ltd. (hereinafter referred to as “DHPH”)
- [LE1955]_Kunming Dihon Pharmaceutical Sales Company Ltd. (hereinafter referred to as “KMDH”)
- [LE1956]_Shanghai Dihon Pharmaceutical Company Ltd. (hereinafter referred to as “SHDH”)
- [LE1958]_Sichuan Dihon Pharmaceutical Development Company Ltd. (hereinafter referred to as “SCDH”)

This Directive applies to common types of services that HCPs are permitted to provide according to the RDPAC Code and applicable regulations: HCPs may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration.

Bayer China may contract non-HCP individuals or legal entities to provide services. In case there is no such policy, this Directive should be applied to the greatest extent as long as in line with all applicable laws and regulations.

Please note that this Directive also includes a provision on services rendered by Government Officials (see, section 2.7).

1.3 Effective Date

This Directive is effective from April 3, 2017.

1.4 Primary Version

The primary version of this regulation is the English version. The Chinese version is the translation of the English version. In case the Chinese version does not conform to the English version, the English version prevails.

1.5 Review Frequency

This Directive should be reviewed once a year or earlier if necessary.

1.6 Definitions

“Bayer China” means all the legal entities in the mainland China. It includes Bayer China Limited and its subsidiaries, affiliates and branches and representative offices in China.

“Bayer Product” means all products that are manufactured or in-licensed by Bayer.

“Contributor” means an HCP who participates as an expert on the topic of the meeting and makes a significant contribution. A contribution is considered as significant if the contributor actively participates in and comments during an entire event.

“EFPIA” is the abbreviation of European Federation of Pharmaceutical Industries and Associations which represents the pharmaceutical industry operating in Europe.

“Events” comprise Self-organized Events and Third Party Events. They do not include internal events.

"Government Official" shall comprise “State Employees” and “Quasi State Employees”.

- "State Employees" mean personnel working in government agencies, e.g. officials of the ministries, administrations and bureaus at the central level, such as National Health and Family Planning Commission, China Food and Drug Administration, etc., as well as officials of the local government at different levels and in different agencies, such as local health authorities and Food and Drug Administrations.

- "Quasi State Employees" mean personnel who are deemed as State Employees, who shall consist of:

    - Personnel working in state-owned companies and enterprises, public institutions and social organizations that carry out public duties; and

    - Personnel that are dispatched by state-owned companies and enterprises, public institutions and social organizations to entities other than state-owned companies and enterprises, public institutions and social organizations, and that carry out public duties; and

- Other personnel that carry out public duties in accordance with laws.

E.g., in China, Quasi State Employees usually include directors of state-run hospitals, but do not include doctors, nurses, pharmacists and other HCPs in general.

"HCP" means Healthcare Professional, i.e. 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.

“OPERA” means the Event approval IT system in Pharmaceuticals and Consumer Health.

“RDPAC” means R&D-Based Pharmaceutical Association Committee (in China).

“Scientific Publication” means any external communication relating to a research molecule, an investigational drug or a marketed product within Bayer’s pipeline or portfolio that aims to disclose the findings of research, whether laboratory, clinical, literature-based or other, and is intended for submission to a scientific congress, presentation in public to a scientific audience, or publication in a peer-reviewed journal. Examples of scientific publications include abstracts, slide presentations, satellite symposium presentations authored and presented by Bayer personnel, primary papers, review articles, journal supplements, letters, short reports and other brief journal communications.

“Self-Organized Event” means a symposia, congress, meeting, or training organized by Pharmaceuticals and Consumer health with the purpose of informing HCPs and/or other Third Parties about products and/or to provide scientific or educational information.

“Small Event” means a Self-organized Event with total budget not exceeding CNY10,000 (including speaker fee).

“Third Party/Parties” include, but are not limited to associations, hospitals and distributors. Other Bayer Group companies and employees are not considered as Third Parties for the purpose of this Directive.

“Third Party Event” means a congress, symposium, meeting, or training organized by a Third Party with the purpose of providing scientific and/or educational information to HCPs and/or other Third Parties.

2 General Principles

2.1 No Inappropriate Influence

Bayer China's interactions with any Third Party must at all times be ethical, appropriate and professional. Nothing should be offered or provided by Bayer China in a manner or on conditions that would have an inappropriate influence.

Bayer China must have an actual, bona fide and objective business need to hire the particular contract partner; even the perception that a service agreement is misused as a “hidden” inducement for sales or prescription-related activities must be avoided.

A legitimate need for the services must be clearly identified and documented in advance.

2.2 HCP Engagement

HCPs may be engaged as consultants and advisors for services specified in this Directive. (For OPERA users, please follow the system instruction. For Non-OPERA users, please see attachment “Att-1 Application Form for HCP Service”.)

The selection of consultants must be exclusively based on objective criteria, including but not limited to education, knowledge, expertise and experience in a particular therapeutic area, etc., which shall be directly related to the identified need of the services. The selection of consultants must be validated prior to commencement of the services by departments with sufficient expertise and full independency from sales function, in order to evaluate whether the consultant satisfies the above objective criteria and is able to fulfill the identified need.

A certain prescription level is never an allowable reason to conclude an agreement with an HCP.

Bayer shall not employ nor pay anyone (including HCPs) to collect or provide such information as patient case or prescription data.

2.3 Fair Market Value

The compensation made to HCPs in conjunction with services should be reasonable and based on Fair Market Value.

Bayer China established service fee standards to ensure the payment made to HCPs is in line with Fair Market Value in Mainland China. (Please see attachments “Att-2 Classification of Speaker Level” and “Att-3 Service Fee Standards”.) HCP service fees may vary depending on (i) the different levels of the HCP engaged and (ii) the duration of the service an HCP provides (see below, section 3.1.2). In parallel, an annual total fee limit (payment within one year) is set up accordingly. Exceeding such standards may only be permitted under exceptional circumstances and shall be approved by at least two Division Management Team Members in advance. Regularly, the Head of Medical and/or Compliance should be among the approvers. (For OPERA users, please follow the system instruction. For Non-OPERA users, please see attachment “Att-4 Application Form for Payment to HCP Exceeding Annual Total Fee Limit”.)

The Fair Market Value for HCP services in different countries can be checked on the internal website: http://pharmatoday.bhc.cnb/APPS/BSP/DE/BSP-Compliance/BSP-Compliance.nsf/id/EN_Guidelines?open.

In case that Bayer China engages a foreign HCP to provide services in Mainland China (e.g. deliver a speech during a Bayer China satellite meeting in Mainland China), the compensation shall be in line with the FMV requirements of his or her respective home country.

2.4 Multiple Roles

If an HCP plays several roles within the scope of Speaker, Chairperson and Contributor, or gives more than one presentation on the same or similar topic in the same Event as a

Speaker (usually at the same venue and to the same audience), the speaker fee can only be paid once and should not exceed the maximum amount in the service fee standards.

Example:

Bayer China runs three satellite symposia (Xarelto, Aspirin, Glucobay) at a scientific congress and invites a national Key Opinion Leader (below refer to as "KOL") to be a chairperson or speaker at all three of them. The three symposia are seen as separate Events. The national KOL can be paid for each Event separately.

Bayer China organizes a two-day City Meeting about hypertension. A local KOL is invited to present two different topics. The local KOL can be paid for each presentation separately.

Bayer China organizes an Experience Sharing Meeting. A regional KOL is invited to chair the meeting and to present one patient case. The KOL can only be paid one time.

2.5 No Cash Payment

All Service Fees under this Directive shall be directly contracted and paid by Bayer China via bank transfer (cash (or cash equivalent, such as a voucher) or third party payments are not allowed).

2.6 Written Agreement

HCP services and relevant payments must be based on written agreements whose templates have been approved by Bayer China Legal Department. The agreements must include details of the required services and compensation and must be agreed in advance of the commencement of the services. (For the Professional Service Agreement template, please contact Bayer China Legal Department: http://sp-coll-bbs.ap.bayer.cnb/sites/000157/Legal/Legal/Contract%20Templates/default.aspx)

2.7 Service of Government Officials

Any monetary payment to State Employees is prohibited in Bayer China. Therefore, they may not be contracted to provide service to Bayer China.

Quasi State Employees, e.g. directors of state-run hospitals, can be engaged to provide services to Bayer China. In case of doubt, the Bayer China Compliance Department shall be consulted for advice.

2.8 Employer Approval

If an HCP is engaged to provide service to Bayer China, he/she should ensure having obtained necessary approval from his/her employer before the provision of service. The Third Party should confirm having obtained the necessary approval when signing the service agreement with Bayer China.

2.9 Mandatory Training

Any new employee of Sales and Marketing should not independently conduct business relating to HCPs before completing the on-boarding Compliance training and other mandatory trainings.

2.10 Cross Border Service Agreements

If Bayer China engages a foreign HCP as Speaker, the following principles apply:

Each cross border agreement has to undergo a check by the compliance officer of the HCP's country of primary practice (home country) regarding relevant compliance requirement and fair market value.

For this check the draft agreement shall be sent to the (Code) Compliance Officer of the HCP's home country by email.

A list of Bayer Compliance (and Code Compliance) Officers of other countries is available at the following link: http://pharmatoday.bhc.cnb/APPS/BSP/DE/BSP-Compliance/BSP-Compliance.nsf/id/EN_complianceOfficersMap.

3 Permissible HCP Services

3.1 Services during Events

An HCP can be engaged to provide services during Events as

- Speaker
- Chairperson
- Contributor
- Interpreter

and can be reimbursed based on Fair Market Value. (Please see attachment "Att-3 Service Fee Standards".)

The Events' agenda must clearly reflect the provision of particular services by participants.

3.1.1 Number of Service Provider

The number of selected HCPs should not exceed the basic business need (please refer to specific Event Catalogue).

- A Small Event organized by medical representatives shall have as an absolute *minimum* no less than 4 external participants (including the speaker).

- The number of speakers for a Small Event should generally be no more than 1 or 2 speakers including chairperson. In any case, a maximum of 3 speakers per Small Event must not be exceeded (including speakers, Contributors and/or chairpersons) and the number of speakers must not exceed 30% of all external participants of the

Event. For example, if a Small Event has 9 external participants, the number of speakers and chairpersons for this Event should be no more than maximum 2. Otherwise, special approval by Bayer China Compliance department is required.

- Considering the content of the Event's discussion, having a chairperson must be justified and the planned contribution of the chairperson must be specified in the Event agenda. In any case, the number of chairpersons must be reasonable. There should be no more than two chairpersons per half-day Event (including satellite meetings and side Event). Any exceptions require the prior approval from the Compliance Department. A half-day Event usually lasts for at least 3 hours and a full-day Event usually lasts for at least 6 hours. Generally, the chairperson's pre-defined contributions (specified in the agenda) should be no less than 10 minutes, including opening and closing remarks. The chairperson must be present during the entire Event and function as moderator of discussions.

3.1.2 Duration of Service

Any speaker shall have no less than 30 minutes of lecture time per meeting.

Exceptions are only allowed in the following cases:

- Experience sharing meetings (organized by district managers or level above and further defined in the Event Catalogue); if the speech time is less than 30 minutes, only 1/2 of the standard speaker fee can be paid.
- Satellite meetings during Third Party Events; if the speech time is less than 30 minutes, 2/3 of the standard speaker fee can be paid.
- Events taking place in the framework of projects that have been pre-approved by Bayer China Compliance Department; if the speech time is between 20 and 30 minutes, 2/3 of the standard speaker fee can be paid, if the speech time is between 15 and 20 minutes, only 1/2 of the standard speaker fee can be paid.

In any case, if the speech time is less than 15 minutes, no speaker fee shall be paid.

The requirements mentioned in this section 3.1 also apply to presentations of HCPs given during **online Events**.

3.1.3 Event Catalogue

A dedicated Sales and Marketing Self-organized Event Catalogue ("Event Catalogue") has been agreed by Compliance Department with the relevant functions. The Event Catalogue stipulates detailed permissible numbers of service provider as well as permissible service duration for each type of Event. The Event Catalogue, as a binding document related to this directive, has been published on the "Bayer China Compliance Portal", and must be used as the guidance for arranging any Sales and Marketing Self-organized Events and engaging HCPs to provide services. In case of doubt, Compliance Department shall be consulted.

3.2 Other Service

Bayer may contract HCPs to translate Scientific Publications for its specific business need provided that such arrangements are in line with all applicable laws and regulations.

All Bayer product-related scientific publication translations should be approved by Medical Affairs.

Besides translating Scientific Publications, any other service type should be permitted by Compliance and Legal case by case in line with all applicable laws and regulations.

4 Documentation and Reporting

All kinds of mandatory documentation relating to engagement of HCP must be submitted to the company though system or with hardcopy for the purpose of pre-approval or payment. An overview of Compliance required mandatory supporting documents for pre-approval as well as for payment included in Attachment 5- Compliance Required Mandatory Supporting Documents for Pre-Approval and Payment of Compliance Principle for Events Directive [Regulation No.: Compliance-009] shall be referred to.

In accordance with the Compliance Principles for Events Directive, all relevant documentation requirements for Events must be observed (including agenda, sign-in sheets of participants and photos both of the audience and the speaker). For the avoidance of doubt, sign-in sheets of participants are also required for so-called “speaker-only Events” in which no meals will be offered to the participants. In addition, the photo of the speaker must be taken during the delivery of speech and should generally also show the presentation slides.

Bayer China shall document and disclose all EFPIA reporting relevant transfer of value it makes, directly or indirectly, to HCPs with country of regular working place in EFPIA region. (E.g. if Bayer China engages a German HCP to provide speaker service for Bayer China, it should be documented and disclosed.) The Requester can check through the following link for instruction of Crystal process: https://crystal.bhc.cnb/. In case of doubt, Compliance Department shall be consulted.

5 Attachments to this Directive

The latest effective attachments to this Directive can be found and downloaded on two intranet sites, i.e. “China Regulation Online”, address: http://china-regulation.ap.bayer.cnb/cms/index.html，and “Bayer China Compliance Portal”, address: http://sp-coll-bhc.ap.bayer.cnb/sites/250003/Compliance_CHN/SitePages/Home.aspx.

Attachment list:

Att-1 Application Form for HCP Services

Att-2 Classification of Speaker Level

Att-3 Service Fee Standards

Att-4 Application Form for Payment to HCP Exceeding Annual Total Fee Limit