[The main version is English version, Chinese version is translated version, if the two of them are inconsistent, the Chinese version is subject to the English one]

Guidance on Events and Communication with External Persons

1. Scope

This guidance is applicable to communication with external persons during events and /or other interactions in Bayer Pharmaceuticals (incl. Radiology) and Consumer Health.

2. Definitions

2.1 Events: in this text, events include Self-organized Event and Third party Event.
Self-organized event: according to Bayer Code Compliance directive "Compliance Principles for Event", it refers to 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.
Third party event: according to Bayer Code Compliance directive "Compliance Principles for Event", it refers 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 Parity. Support on continuing medical education ("CME") accredited activities should follow local process on CME review.

2.2 Healthcare Professional ("HCP"): it 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. In this text, HCPs exclude non-pharmacist pharmacy staff.

2.3 Medical Inquiry Medical Inquiry is an unsolicited customer request for scientific or medically relevant information about marketed or non-marketed Bayer products from the Pharmaceutical and Consumer Health divisions. **Off-label Inquiry** is an inquiry regarding the use of a medicinal product not in accordance with the authorized product information. **Un-approved Use Inquiry** is an inquiry regarding a medicinal product in a country in which it is not approved by the Regulatory Authority.

2.4 Medical Information Personnel is a medical staff with the appropriate training, education and experience or any combination thereof, to perform their specific role as part of the medical information process, including Country Medical Director ("CMD"), Medical Communications ("MC"), Medical Advisor ("MA") and Medical Scientific Liaison ("MSL") .Detailed please refer to local OI on medical inquiry handling process.

2.5 Off-label Use is an intentional use of a medicinal product not in accordance with the authorized product information. Off-label Use must in no way be encouraged, supported or solicited by Bayer employees.

Off-label use is exampled as below.

	Examples	
	Content in approved label	Off-label use
Indication	Advanced hepatic cancer	NSCLC
Prevention of diseases	None	Heart attack
Dose	Maximum 10 mg per day	30 mg per day
Treatment choice	Second line treatment	First line treatment
Target group	Adult	Adolescent
Treatment period	Acute stage	Maintenance stage
Drug administration mode	Treatment with single drug	Combination therapy

2.6 Social Media and Website refer to the social media/social media account/website for external use which is owned or sponosred by Bayer Pharmaceuticals and Consumer Health (excluding Dihon cosmetics) . The proposal of social media and websites should be reviewed by Corporate Communcations, IT, Medical Affairs, Pharmacovigilance beforehand, and local process on social media and website checklist should be followed.

2.7 Sales and Marketing people refer to the personnel who are responsible for marketing and sales activities, including but not limited to staff of Sales Department and Marketing Department.

3. General Principles

3.1 Principles in hospital visits

1) The followings are allowed for Sales and Marketing people

- Visit HCPs who treat patients with approved indications.
- Disseminate approved* product information to HCPs.
- Disseminate approved* external communication material to HCPs. Early cancelled or expired material should be recalled and destoryed according to local OI CN-OI-007-BPD.
- Disseminate approved* published literature data with permissible copyright and within approved label.
- Refer discussion or issue on Investigator/Institution Initiated Research (IIR) or Bayer initiated studies (e.g. Observational Studies (OS), Interventional Post-Approval Trials (IPAT), etc.) to Medical Department.

2) The followings are <u>NOT</u> allowed for Sales and Marketing people

- Visit HCPs who do not treat patients with approved indications.
- Disseminate any off-label product information to HCPs.
- Modify any approved* extermal communication materials for use.
- Disseminate any unapproved* extermal communication materials to HCPs.
- Discuss with HCPs on topics beyond approved labels.

* "approved*" means materials are approved via global review sytem; for materials in scope of advertisement defined in drug advertisement law, "approved" also means materials are additionally approved by health authority.

- Discuss with HCPs about study protocol or study issue, organize investigator meetings or intervene in study conduction (e.g. patients enrollment).
- Disseminate any "internal use only" materials to external parties.

3.2 Principles in self-organized events

1) The followings are allowed for Sales and Marketing people

- Organize events for HCPs who treat patients with approved indications.
- Introduce product information within the approved label to HCPs at events.
- Disseminate approved* published literature data with permissible copyright and within approved label at events.
- Use approved* and valid external communication materials at events, including presentation slides prepared by external experts.
- When HCP is invited as the speaker, event owner should brief the speaker about the obligations as speaker in Bayer events, including global review system approval requirements (timely submission of slides for Bayer review and no modifications after approval), and he/she cannot proactively introduce any off-label information of Bayer product at the event, when responding to an off-label inquiry regarding a Bayer product information at the event, he/she should clearly state that the product is not yet approved in China for that indication.
- Early cancelled or expired material should be recalled and destoryed according to local OI CN-OI-007-BPD.

2) The followings are <u>NOT</u> allowed for Sales and Marketing people

- Organize events (including but not limited to hospital department meetings) for HCPs who do not treat patients with approved indications.
- Provide off-label information to HCPs for speech at event.
- Use unapproved* or expired slides/documents/ materials at event.
- Modify any approved* external communication materials for use.
- Disseminate literature data that is unapproved*, without permissible copyright, or contains off-label information at events.
- Dissemniate any "internal use only" materials to external parties.

3.3 Principles for activities before NDA approval

Pharmaceutical product is not allowed to be promoted for use in China until marketing authorization has been granted by China Food and Drug Administration (CFDA).
The activities before NDA approval must be non-promotional in nature and should be led /organized by Medical Department.

1) The followings are allowed for Sales and Marketing people

- Provide logistics support for the medical activities before NDA approval, e.g. provide contact information of HCPs, etc.
- Marketing people just can listen-in at external medical activities on the premise that the participant number is limited and permissible.

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2) The followings are <u>NOT</u> allowed for Sales and Marketing people

- Lead / organize activities before NDA approval.
- Marketing people are not allowed to speak and involve in discussion with HCP in external medical activities.
- Sales people are not allowed to attend at external medical activities.
- Promote unlicensed product or off-label information of licensed product.

3.4 Principles in Drug-Related Retail activities

3.4.1 Applicable for Pharmaceuticals

1) The followings are allowed for Sales and Marketing people

- Use approved* external communication materials for pharmacist education, the materials should be noted that" 仅供与医疗卫生专业人士学术沟通使用 (for scientific communication with HCPs only)".
- Early cancelled or expired material should be recalled and destoryed according to local OI CN-OI-007-BPD.

2) The followings are <u>NOT</u> allowed for Sales and Marketing people

- Provide prescription product branded (with product name/logo) materials, or materials containing OTC product name but without advertisement approval by health authority (with the exception of the materials only containing brand name) to non-HCPs.
- Modify any approved* external communication materials for use.
- Use unapproved* or expired external communication materials for pharmacy activities (e.g. using handwritten poster to introduce Bayer product).
- In-store promotion for prescription products (e.g. Display prescription products or its package in open area/ on-shelf). Regarding OTC product, publish advertisement without advertisement approval by health authority.

3.4.2 Applicable for Consumer Health

1) The followings are allowed for Sales and Marketing people

- Provide approved* and valid external communication materials to pharmacy staff and pharmacist. Early cancelled or expired material should be recalled and destoryed according to local OI CN-OI-007-BPD.
- Use approved* and valid external communication materials for pharmacy staff and pharmacist education activities, and confirm the education materials are noted "仅供药店内部培训使用(for pharmacy internal training use only)"

2)The followings are <u>NOT</u> allowed for Sales and Marketing people

- Disseminate off-label information to pharmacy staff and pharmacist.
- Modify approved* external communication materials for use.
- Disseminate unapproved* or expired external communication materials to pharmacy staff and pharmacist.
- Use unapproved* or expired external communication materials for pharmacy activities (e.g. pharmacy internal education, using handwritten poster to introduce Bayer product).
- Use approved* hospital channel used external communication materials for pharmacy activities(e.g. pharmacy internal education)
- In-store promotion for prescription products (e.g. Display prescription products or its package in open area/ on-shelf).

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3.5 Principles in Continuing Medical Education Sponsorship

Based on whether third party program funded by Bayer is CME-accredited, Bayer sponsorship support is categorized into:

- "Purely CME sponsorship" means Bayer only provides sponsorship for accredited programs (e.g. symposium/section and speaker fees in event agenda, online meeting materials development and platform setup)
- "Purely commercial sponsorship" means Bayer only provides sponsorship for non-accredited activities (e.g. booth/stand/advertising place, logistics, meals, and certain non-accredited satellite meetings, invitation of HCPs/registration fee)
- "Mixed sponsorship" means Bayer provides sponsorship for accredited programs and non-accredited activities.

1) The followings are allowed for Sales and Marketing people

- Support purely commercial sponsorship.
- Support mixed sponsorship approved by Medical CME responsible.

2) The followings are <u>NOT</u> allowed for Sales and Marketing people

- Support purely CME sponsorship. Purely CME sponsorship must be supported by Medical.

3) Rules for supporting:

- Bayer must not influence, advise, or provide guidance to the agenda and/or the content of the third party CME, neither the faculty, optional steering or advisory committee members;

3.6 Principles in Patients Education ("Patient Support Program" and "Self-organized patient education in Consumer Health" please refer to other procedures.)

Self-organized patient education is prohibited for prescription product.

1) The followings are allowed for Sales and Marketing people

- Sponsor patients education initiated by third party (healthcare institutions /associations) and disclose the sponsorship as "sponsored by Bayer".
- Provide approved* materials containing the following information to third party who initiates patients education: disease information and available therapies (without Bayer prescription product branding information); disease publications (without Bayer prescription product branding information).

2) The followings are <u>NOT</u> allowed for Sales and Marketing people

- Provide unapproved* materials to the initiatior.
- Provide materials containing promotional information of prescription product to the initiator, including: product name (including brand name and generic name if Bayer drug is the unique one which the generic name could indicate), product logo, or any other wording which can be/may be interpreted as product promotion to public.
- Promotion to patients via third party initiated patient education activities (including but not limited to: mentioning Bayer prescription product information, or information beyond product name for OTC product.).

3.7 Principles in response to medical inquiries

Medical inquiries related to Off-label/Unapproved Use received by any Bayer China employee (except Medical Advisor, MSL, Medical Communications (MC) personnel) must be routed to MSL or MC personnel for answering

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and be documented in Information Request Management System (IRMS). Responses to such medical inquiries must only provide specific information answering the specific question and the responses must always contain information regarding locally the approved labeling.

1) The followings are allowed for Sales and Marketing people

- Respond to on-label inquiries with information that is covered in the local approved label.
- If additional research is required for on-label inquiries, forward the inquiries to MSL or MC personnel for response.
- When asked for information on Off-label/Unapproved Use, inform HCPs that relevant indications or products have not been approved in China yet, and forward the inquiries to MSL or MC personnel for answering; or directly inform HCPs about the contact information of MSL or MC personnel.

2) The followings are <u>NOT</u> allowed for Sales and Marketing people

- Answer inquires related to Off-label/Unapproved Use directly.
- Provide data related to Off-label/Unapproved Use to HCPs.

3.8 Product Safety Information Reporting

The principles must be followed by all Bayer employees:

- Product safety information must be forwarded to Pharmacovigilance (PV) Team immediately and within 24 hours after receiving it.
- When Bayer develops and/or markets their products in collaboration with external Partners, regulatory authorities require written agreements on the exchange of safety related information between contract partners and on their reporting responsibilities to authorities.

If you have any questions about what constitutes off-label promotion or require any guidance about promoting Bayer products, please contact Medical Compliance and/or Legal colleagues.