

Code of Practice for Promotional and Non-promotional External Interactions

All GSK Pharma and Vaccines Business Units

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Why do we have this Policy?

Purpose

The Code of Practice:

- Provides principles for our external interactions that aim to enhance the understanding and appropriate use of GSK medicines and vaccines (referred together as *medicines* in this Code) for the benefit of individual patients and populations.
- In conjunction with our supporting policies and procedures, enables us to conduct our external interactions in a way that adheres to relevant laws, regulations and external codes.

GSK's Chief Medical Officer (CMO) is accountable for the approval of the Code. **Medical and Commercial Leads** are responsible for implementation of the Code.

It describes the principles for:

- Promoting prescription medicines to *Healthcare Professionals/ Other Healthcare Staff* (HCPs/OHS).
- Non-promotional activities.
- HCP payments and transfers of value.

① *Promotion* is any activity directed to HCPs/OHS, where the intent is to encourage sales, purchasing, prescribing or recommendation of an authorised medicine. Activities include but are not limited to the use of promotional materials, promotional meetings and detailing. Direct to consumer advertising is addressed separately below. Creation of materials or organization of meetings by GSK do not by themselves define an activity as promotional.

① Non-promotional activities can be directed to HCPs/OHS or non-HCPs with the intent to improve patient care through the exchange or provision of knowledge on the use of our medicines and related diseases. Non-promotional activities include but are not limited to scientific interactions (Scientific Engagement), support of medical and disease education, advice seeking, scientific communication of our research, and disease awareness for the general public and patients. The term “patients” includes people who receive our vaccines.

① For guidance on how to implement all in-scope activities, refer to the *Code Toolkit*.

① The conduct of clinical research, other R&D activities, regulatory interactions, market research and media activities are covered in detail by other written standards.

Symbol Key:

★ Critical action; 👁 Monitoring item; ⓘ Helpful tip

Who needs to follow it?

Document Audience Scope

The Code applies to all staff in Vaccines and Pharma (including R&D and Commercial functions), and those who work on our behalf, who are involved in any of the in-scope activities.

ViiV Healthcare and Consumer Healthcare follow separate codes.

What do you need to know / do?

Principles

Key Principles

We adhere to local laws, regulations, applicable binding sections of industry codes, this Code of Practice and applicable GSK policies (e.g. Anti-Bribery and Corruption Policy). In the case of conflicting requirements, the one which is most strict is followed.

① Where the GSK Code of Practice or local industry codes do not cover specific aspects, or where local or regional industry codes do not exist, the IFPMA Code of Practice applies.

Principles for promotion and non-promotional activities

- Activities never discredit or reduce confidence in GSK or our industry.
- We do not offer or provide anything of financial value that is intended to influence the recommendation, prescription, purchase, supply, dispensing or administration of our medicines.
- We do not seek to gain access or obtain an appointment with HCPs/OHS using any inducement or deception.

Our verbal, printed and digital information and communications are:

- Clear, legible, up to date, accurate, fair, objective and balanced (i.e. we do not overstate efficacy, understate safety or make unsubstantiated comparisons).
- Transparent about GSK's specific involvement, and any conflicts of interest are disclosed.
- Capable of substantiation (i.e. based on data or other evidence that can be provided or referenced).
- Based on relevant evidence and sufficiently complete to enable the recipient to form an opinion of their own.
- Never knowingly offensive or disparaging.

① See Policy for use of digital channels.

Principles specific for Promotion

We only promote medicines to HCPs/OHS:

- In a country after marketing authorisation has been granted for that country.
- For approved indication(s), consistent with locally approved prescribing information.
- Whose need and interest in the information can be reasonably expected based on the locally approved prescribing information.

Principles for direct to consumer advertising

We only advertise medicines to the general public:

- In those countries where it is permitted by local laws, regulations and applicable industry codes, or
- When it is a public health activity such as a vaccination campaign approved by relevant authorities.

Principles for non-promotional activities

These principles are applicable from discovery, through development, to post-authorisation of our medicines:

- We engage in external interactions to increase external understanding of diseases and use of our medicines. In addition, we engage in external interactions to increase our understanding so that we can develop or improve medicines and support appropriate use of our approved and future medicines.
- Based on the type of information shared, external interactions can be proactive or reactive, on label, consistent with label, or off label while fully respecting local laws, regulations and applicable industry codes.
- Any perception of promotion in connection with proactive non-promotional activities must be avoided.
- Information which is shared does not ask for a prescription to be made based on any conclusions and is not designed or conducted to increase sales, purchase, prescription or recommendation of the use of our medicines.
- Support for healthcare services achieves enhanced patient care, better healthcare outcomes or improvements to a healthcare system.

Principles for engagement, payments and transfers of value when contracting external experts for services

Our engagement with *External Experts* as investigators, authors, advisors and speakers is vital to the development and delivery of our medicines. At the same time, HCPs/OHS maintain independence in decisions relating to the management of patients in their care. Therefore:

- We only engage an external expert when there is a legitimate need and the external expert is identified as an appropriate individual for the service required. We identify and manage conflicts of interest and ensure that a written agreement is in place before work is started.
- We may provide an external expert with a fair market value payment for certain non-promotional services (e.g. consultancy, facilitation of scientific workshops). Payments and transfers of value are appropriately disclosed where applicable.

- We may also provide a fair market value payment to selected external experts to speak on our behalf about our medicines or associated diseases during promotional events, but only in specified countries for selected programmes.
- We do not pay external experts who have an influence on government that may impact GSK business (Anti-Bribery and Corruption Policy).

① See Procedure for Engaging with External Experts to Provide Services.

We do not provide direct financial support to individuals to attend medical congresses or associated satellite symposia as delegates. We may provide indirect support for external experts to travel and attend medical congresses by providing funds to the congress organiser or other independent third parties to whom the external experts can apply. Selection of external experts to receive funding is made independently from GSK by the third party.

In countries where we may pay HCP fees for service for selected promotional programmes, we may also fund and arrange travel and accommodation for invited delegates to attend our stand-alone promotional meetings.

Accountability and Decision Making for promotional and non-promotional activities

Decisions are made at the appropriate level of the organisation and preferably at the level at which an activity is organised without unnecessary escalation to higher management. The responsibility for certain decisions may be delegated by the accountable person depending on the scale, impact and risk of the activity. Such delegation is documented.

The General Manager (GM) as country head has overall accountability for all local level promotional and non-promotional activities and related processes. Decision making by the GM, in consultation with all relevant functions, is in accordance with company policies and legal and regulatory requirements. The GM retains the right to suspend or cease any promotional or non-promotional activity at any time. Any escalation required follows the principles defined below.

Accountability for Promotional activities

The commercial function (e.g. GMs or Global Commercial Leads) is accountable for decision making for promotional activities and other commercially led activities (e.g. market research) in consultation with other relevant functions. There are however processes which contribute to decisions over promotional activities which require approval by other functions (e.g. Copy approval of commercial material) before execution. When escalation concerning a local level decision is necessary, it is to the respective Regional Commercial Head, and for Global level decisions it is to the Global Commercial Therapy Area Head or Head of Global Vaccines Commercial as appropriate.

Accountability for Non-promotional activities

The medical function (e.g. Country Medical Director (CMD) or CMO) is accountable for decision making for non-promotional medical activities and other medically led activities in consultation with other relevant functions.

In the pre-approval setting the Medicine or Vaccine Development Leader has decision making authority until a Global Medical Affairs Leader (GMAL) is appointed at which point authority would be handed over. Escalation of decision making is to the respective CMO.

In the post-approval setting at country level the CMD, and at above country level the GMAL, have decision making authority. Escalation of decisions at a local level is to the Regional Medical Director, and at Global level to the Business Unit CMO.

Decision Making

For most activities, application of the principles in this Code and adherence to the related processes provides a strong foundation for mitigation of key risks, such as inappropriate promotion, bribery and corruption, and inappropriate payments to third party individuals/organisations. However, all activities retain a degree of residual risk which needs to be assessed and mitigated in the decision-making process.

When a decision requires judgement due to uncertainty about the way forward, we apply the GSK values of transparency, respect, integrity and patient focus (TRIP) (Code of Conduct) and take into consideration the timing, intent, proportionality and perception (TIPP) of the proposed activity and consult with Business Partners and Subject Matter Experts as appropriate to make the decision. Application of TRIP and TIPP includes but is not limited to:

TRIP:

- Transparency: Materials and activities that we initiate, arrange or fund, clearly disclose GSK's specific involvement. Payments and transfers of value are appropriately disclosed.
- Respect for people: Activities never discredit or reduce confidence in GSK, our industry or anyone else. GSK corrects misinformation about our medicines or diseases through transparent, truthful dialogue.
- Integrity: Activities are carried out in a responsible, ethical and compliant manner.
- Patient focus: Activities enhance healthcare and benefit those who use our medicines.

TIPP:

- Timing: There is an appropriate need for the activity at the time it occurs. The status of marketing authorisation, availability of data for external use, and the alignment with other GSK or external events are considered before each activity.
- Intent: Our intention is to either strengthen knowledge (including about our medicines), or to promote our medicines, and this distinction is made clear to the external audience. The need for a promotional or non-promotional activity is clearly specified and documented as part of a defined approval process.
- Proportionality: The scale and frequency of each activity are appropriate for the need, as are the selection of presenters, advisors and participants.
- Perception: Non-promotional activities are not perceived to be promotional and our promotional activities are not disguised. There is no undue influence or hidden conflict of interest.

What monitoring is required for this policy?

GSK's Internal Control Framework (ICF) requires that management have appropriate monitoring in place to address and reduce company risks. GSK's Enterprise Risk Plans (as adapted by businesses and functions) outline monitoring expectations for management to facilitate effective risk management.

Questions on risk management and monitoring can be raised to your business area Ethics & Compliance Business Partner, the Enterprise Risk Management Team in Global Ethics and Compliance, your embedded risk management group (if applicable), or the aligned Enterprise/ Business/Function Risk Owners.

Glossary

Definitions of terms stated in this document in *italics* can be found in the online GSK Written Standards Glossary

Where to raise questions, concerns or exceptions

If you are unsure about how to apply this policy, or feel you need to raise an exception to it please bring this to the attention of a manager .



If you see any violations of this company policy, please report it through the appropriate Speak Up channels. To find your local Speak Up integrity line number or to report online, please visit: www.gsk.com/speakup

Administration

Document Governance

Effective Date	11-NOV-2020
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Version History and Changes

Current Version:	Code of Practice for Promotion and Non-promotional External Interactions (8.0) Changes since last revision: <ul style="list-style-type: none">- Changed from STD to Policy- Reduced content to only contain principles. Other mandatory content moved to relevant SOPs.
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