Marketing Practices and Scientific Engagement

The Issue

GSK is committed to responsible, principled and patient-centred external interactions with the healthcare community. Our interactions conform to ethical, medical and scientific standards that are determined by law and regulation, promoted by industry associations and embraced by the company. They are also consistent with our company values of transparency, integrity, patient-focus and respect.

All GSK marketing and promotion is based on valid scientific evidence, consistent with national prescribing information for prescription medicines - or relevant regulations for non-prescription medicines and consumer healthcare products. It complies with all applicable laws and regulations established at national levels, observes all industry Codes and aligns with the global principles set out in our own Codes of Practice for GSK pharmaceutical, vaccine and consumer healthcare products.

We recognise the importance of engaging with external stakeholders to progress medical science and to meet the needs of patients and public health. Our physicians and scientists engage in the highest standards of peer-to-peer scientific dialogue to increase understanding of diseases and to develop effective prevention and treatment therapies. The activities and materials associated with scientific engagement are non-promotional in nature and intent.

This paper summarises the principles underlying GSK’s approach to marketing and to scientific engagement and highlights how we align with regulatory and industry requirements. It concludes by focussing on the importance GSK attaches to training those who engage with HCPs and on the programme we have in place to ensure compliance with our standards.

GSK’s Principles

– We only promote our medicines and products in a country after the necessary marketing authorisation has been granted in that country, and only for approved indications consistent with the locally approved prescribing information or relevant national regulations for non-prescription medicines and consumer healthcare products.

– Promotion is only directed at those whose need or interest in the particular information can be reasonably expected, based on the locally approved prescribing information or relevant national regulations for non-prescription medicines and consumer healthcare products.

– We do not use any inducement or deception to gain access to an HCP or to influence the recommendation, prescription, purchase, supply, dispensing or administration of our products.

– Scientific engagement starts in the early stages of development and continues throughout the life cycle of the product. It is driven by legitimate scientific need, is balanced, appropriate and proportional to the scientific need and intent.

– Scientific engagement activities are not promotional; they do not have the appearance of being promotional and are not designed to influence the prescription, supply, sale or use of our medicines.
BACKGROUND

GSK Codes of Practice

All marketing activities and scientific engagement conducted by GSK in the 150+ countries worldwide where we operate must conform to high ethical, medical, and scientific standards as laid out in the global GSK Code of Practice for Promotion of Prescription Medicines and for Scientific Engagement and our Consumer Healthcare Code for Promotion and Scientific Engagement. Where local standards differ from GSK standards, the more stringent of the two applies.

Industry Marketing Codes

In addition to our own Codes of Practice, GSK abides by industry guidelines and codes established by national industry associations, as well as by major international industry associations. These codes and guidelines supplement government regulation and provide guidance and self-discipline for ethical marketing practices. Key examples include:

- In Europe, GSK observes individual country laws, regulations and industry codes, including the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on the Promotion of Prescription-only Medicines to, and Interactions with, HCPs.
- In the United States, we abide by the PhRMA Code on Interactions with HCPs and the PhRMA Guiding Principles on Direct to Consumer Advertising of Prescription Medicines.
- Across Emerging Markets & Asia Pacific, GSK observes individual country laws, regulations and industry codes where they exist, including the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Practice.
- In Japan, we follow additional requirements to satisfy the Japanese Pharmaceutical Manufacturers’ Association (JPMA) Marketing Code.

Training and Implementation of GSK Codes’ of Practice

All GSK sales representatives are trained on the products they promote; on the diseases and conditions the products are designed to treat; and on appropriate marketing practices according to our Codes of Practice and their own national requirements. The training provides a thorough understanding of their obligations and responsibilities. We use the most appropriate training techniques for the sales representatives and products being covered. These include self-study based on company developed materials, one-on-one in-the-field sessions with managers, web-based learning and in-house training courses.

GSK provides training on our Codes of Practice to other employees who require an understanding of the policies, in particular to those in Marketing, Legal, Medical and Regulatory roles. For other employees, the Codes are available for reference.

We expect Third Parties interacting with HCPs and healthcare organisations on our behalf to comply with the standards set out in local laws, regulations, applicable industry codes and our Codes of Practice.

Across GSK, the training and testing of our sales representatives is handled at the individual country level and occurs on hiring and then again on an annual basis. When our Codes are updated, we issue new documentation and train our staff about the relevant changes. Sales representatives are supervised by sales managers who are responsible for ensuring staff meet business objectives while adhering to our Codes of Practice.
GSK’s Scientific Engagement Standards

It is important that GSK actively engages in scientific debate outside the company. This enables us to participate fully in the development of scientific understanding, to benefit from the knowledge of leading external scientists, practitioners and patients and to apply the best possible science to the development of our products. However, we fully recognise the importance of avoiding activities which could be construed as promotion of a new product or a new use of an existing product before we have the necessary marketing authorisation.

To support this, we have implemented clear scientific engagement operating standards for the way we work, to emphasise the distinction between non-promotional scientific dialogue and legitimate promotional activity to support licensed products. These standards apply to all scientific and medical interactions with any external groups, including HCPs, payers, governments, patient groups and the media.

We believe that if our scientific activities appear in any way to be promotional, our credibility will be undermined and we will lose the trust of our stakeholders. Our scientific engagement standards therefore support our aim of being a trusted and valued scientific partner in developing products that enhance patient care.

Facilitating a Culture of Compliance

Beyond ongoing day to day management, there are additional controls to provide oversight of GSK’s marketing practices. Various parts of the organisation, including Finance, Human Resources, Legal, Compliance and Internal Audit, work together to ensure compliance with applicable laws and regulations, industry guidelines and our Codes of Practice, policies and SOPs. Individual business groups/departments have established independent monitoring programmes (e.g. expense account monitoring) and processes to ensure an appropriate level of review and approval prior to activities taking place. For example, all promotional materials and activities must be reviewed and approved according to our Codes of Practice, as well as in accordance with local laws and regulations, to ensure that the materials and activities fairly represent the products or services of GSK (and of third parties). We work consistently to ensure our policies are complied with and remain relevant to the current market and regulatory environment.

In addition, GSK’s internal Audit & Assurance Department reviews sales and marketing activities on a regular basis to ensure proper procedures are in place and adhered to. This audit process provides another way to identify areas that need to be addressed or are a cause for concern, and to make any necessary changes to support comprehensive compliance with our policies.

We Act Upon Code Violations

Any concerns from HCPs, patients or the general public about our marketing practices can be raised with the company through a variety of channels. By encouraging and being open to real and legitimate complaints from any source on any aspect of our work, a more effective and transparent operation exists than would be obtained by relying on internal monitoring alone. Customer response-centre staff are trained to deal with concerns from outside the company and to redirect calls to appropriate senior management or Compliance staff. Where health authorities regulate our activities, concerns can be raised directly with the appropriate government body.

GSK encourages employees, complementary & contingency workers, vendors and any other groups we do business with, to report concerns over possible misconduct, potential conflicts, or known breaches of our Codes of Practice and other company policies and procedures, including our Code of Conduct.
Individuals can speak with their manager, Human Resources professional or Compliance contact or can raise concerns via a website, via post or via a toll-free confidential and anonymous helpline. All concerns are handled promptly, discreetly, and professionally. Discussions and inquiries are kept in confidence to the extent appropriate or permitted by law.

At times, there may be violations of our Codes of Practice or national requirements. When that happens, the priority is to correct the problem as rapidly as possible. Internal violations are dealt with in line with normal company disciplinary procedures and accountable individual(s) are subject to training and discipline as appropriate. When necessary, we dismiss employees who have engaged in misconduct and we have broadened our ability to claw back remuneration from senior management in the event of misconduct.

When a problem is more widespread, the remediation process will likely include control enhancements, significant training initiatives and/or modification of one or more of our policies and procedures as appropriate.

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