Consumer Healthcare Standard

Title: Consumer Healthcare Code for Promotion and Scientific Engagement

Official Short Title: CH Code

Key Points

The purpose of this CH Code is to ensure that, following any necessary authorisation, GSK's activities and interactions with consumers, customers, Healthcare Professionals (HCPs), Other Healthcare Staff (OHS), patient/consumer groups, media, and the general public are carried out in a responsible, ethical, professional, and legal manner.

Why do we have this Standard?

To ensure that GSK Consumer Healthcare activities and interactions are carried out in a responsible, ethical, professional, and legal manner.

What does this Standard say?		Who in CH has general obligations under this Standard?
The Basics	Purpose Scope	**All GSK Staff** ☒
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	3.5. Promotional aids 3.6. Promotions with prizes 3.7. Testing and sampling 4. Promotion to trade customers (not consumers) 4.1. Promotion to customers (e.g. retail and pharmacies) 4.2. Trade investment policy 4.3. Promotional events 4.4. Samples to Customers 4.5. Promotional Aids and Prizes to Customers 5. Promotion to HCPs/ OHS 5.1. All promotional meetings 5.2. Meeting Material (including content of presentations) 5.3. GSK speakers and attendees 5.4. External speakers 5.5. GSK sponsored satellite symposia 5.6. Commercial booths at meetings 5.7. Detailing HCP/OHS 5.8. Medical Affairs/R&D involvement in promotional activities 5.9. Samples to HCPs and OHS to familiarise patients / consumers 5.10. Samples to HCPs and OHS at Congresses and Conferences 5.11. Promotional aids 5.12. Promoting to medical and dental students 6. General requirements for interactions with HCPs/OHS	

	6.1. Engagement of HCPs and OHS to provide services 6.1.1. Annual cap 6.1.2. Records and disclosures 6.2. Meeting venues 6.3. Hospitality 6.4. Funding of third party scientific/medical congresses and other third party meetings 6.5. Funding HCPs/OHS to attend scientific/medical congresses 6.5.1. Selection of medical congresses 6.5.2. Selection of independent third parties (including congress organisers) 6.5.3. Selection of HCPs/OHS 6.6. Funding HCPs/OHS to attend GSK promotional meetings 6.7. Gifts 6.7.1. Cultural courtesy items 7. Other non-promotional activities 7.1. Information about our products for the general public 7.2. Disease awareness for patients or the general public 7.3. Healthcare support services 7.3.1. Patient Support Programmes (PSPs) 7.4. Items of medical/educational utility 8. Co-promotion and third party	

	sales forces 9. Collaboration with GSK Pharmaceuticals (RxCx Collaboration) 10. Endorsements 11. Scientific Engagement	
Glossary and Administration	Glossary Administration Waivers and Exceptions Related Documents Appendix 1: Consumer Healthcare Scientific Engagement Appendix 2: Template for CH Code Local Adaptations Appendix 3: Consumer Healthcare Promotional Aids and Items of Medical/Educational Utility (IMUs) for Individual HCPs	**Contacts:** **Consumer Healthcare Compliance** **Consumer Healthcare Medical**

The Basics

Purpose

Our external interactions follow high ethical and professional standards and reflect GSK values. This ensures these interactions benefit patients and consumers and enhance the understanding of our products.

This CH Code applies to GSK Consumer Healthcare (GSKCH) and provides our global standards for promoting GSKCH products and engaging about our science in a non-promotional manner.

Application and localisation of this CH Code

Other written standards are followed when interacting with specific audience groups or undertaking specific activities which are not included in this CH Code (**see Related Documents** section below). Other key GSK written standards relevant for all our external interactions are all provided in the **Related Documents** section below.

The global requirements provided in this CH Code are followed unless a stricter approach is adopted due to:

- Local or regional specific GSKCH standards or restrictions.
- Local laws, regulations and applicable industry codes.

Throughout the CH Code areas are identified to establish local country level limits and thresholds aligned with other GSK business units in the country. These must be documented in the template attached in **Appendix 2:** *Template for CH Code Local Adaptations*. These local adaptations and specific limits established must be approved by the Country Risk Management and Compliance Board (RMCB). Refer to **Appendix 2** for a template for local adaptations.

Scope

This CH Code applies to activities conducted by or on behalf of GSK Consumer Healthcare.

This CH Code applies to all products within the GSK Consumer Healthcare portfolio. The requirements apply to all Consumer Healthcare products, referred to as "products" unless specifically indicated otherwise as described below.

GSK Consumer Healthcare Products

Prescription Products	Non-Prescription Products	Consumer Products
Medicines and devices that are prescription only by regulatory status and require a prescription for dispensing **Example**: In certain markets Flonase, Panadol Osteo, Voltaren, Lamisil	Medicines and devices that are non-prescription by regulatory status and do **not** require a prescription for dispensing; typically either Over The Counter (OTC), Behind The Counter (BTC), and general sale **Example:** In most markets Panadol, Excedrin, Theraflu	Products that are regulated as food, dietary supplements, nutritionals, cosmetics, medical devices **Example:** In most markets Horlicks, Panoxyl, Sensodyne, Breathe Right, toothbrushes

ⓘ For Medical Devices, the local laws, regulations or industry codes must be applied in determining the product classification they fit into.

ⓘ In some countries, toothpaste and other products may be regulated as medicines. In some cases these products may still be promoted as Consumer Products. Please consult your local Regulatory Affairs contact to determine whether such promotion is permissible.

ⓘ This CH Code does not cover every situation. Our staff apply GSKs values, their judgement and/or additional guidance provided by relevant staff (e.g. line managers, Medical Affairs, Compliance and Legal) when needed.

The Specifics

Responsibilities

All staff follow this CH Code when undertaking the activities described.

Managers of staff involved in activities covered by this CH Code are responsible for ensuring staff are adequately trained on and follow this CH Code.

Managers are accountable for breaches of this CH Code by their staff when the manager knew, or ought to have reasonably known, that such breaches were taking place.

Business owners who select and engage suppliers (such as contract sales forces, consultants, market research agencies, advertising agencies, medical communication agencies, and public relations agencies) and distributors are accountable for ensuring these parties are trained and comply with this CH Code.

Business Development is responsible for ensuring alliance transactions include contractual language that ensures this CH Code will be followed where applicable.

Category and R&D Heads, Area, Hub and Country level General Managers/Country Managers are accountable for ensuring this CH Code is followed.

GSKCH Chief Medical Officer is accountable for the content of this CH Code and Medical Affairs and Legal and Compliance are responsible for governance frameworks to support implementation of this CH Code.

ⓘ Escalation: the order of escalation for questions regarding the interpretation of this document is as follows:

1. Consult with line manager.
2. Consult with Local Medical Affairs representative who, as needed, can escalate through the Medical Governance Board
3. Consult with Country Compliance Manager who will escalate if appropriate.

1. Principles

- Our intentions and actions are driven by our values of consumer focus, transparency, respect for people and integrity.
- Activities and materials created by GSK CH are intended to enhance healthcare and benefit those who use our products.
- Activities that we initiate, arrange or fund and the supporting materials disclose GSK's specific involvement. This declaration of involvement is clearly visible.
- Activities and materials never discredit or reduce confidence in GSK or our industry.
- Activities are carried out and materials are created in a responsible, ethical and professional manner in compliance with regulatory and legal requirements.

ⓘ Where activities or interactions are targeted at individuals from a number of countries or from another country, the relevant Country Medical Affairs leader(s) (or above country Medical Affairs leader, in case there is no dedicated local Medical Affairs Lead) are consulted to ensure applicable requirements are followed. Compliance is consulted as required.

2. Promotion

2.1. Principles for promotion

- Local Regulatory Clearance refers to all applicable regulatory approvals, clearances, registrations or similar requirements as well as all internal procedures required to be completed prior to the marketing or sale of a product.
- We promote in a country only after any local regulatory clearance for the use has been granted in that country. Consult local Regulatory, Legal and Medical on what can be discussed with retail customers and at what stage of the regulatory approval process, including "coming soon" or new product promotions.
- Our products are promoted only for approved use(s), consistent with the local regulatory clearance, with no promotion to HCPs/OHS prior to local market authorisation or regulatory approval.
- Market research to consumers or HCPs/OHS may be conducted prior to obtaining

the local regulatory clearances, please consult with your local Medical Manager.

- Promotion of our products is only directed to those where their need or interest in the particular information can be reasonably expected based on the local regulatory clearance.

- Nothing is offered or provided in a way that has an inappropriate influence on the recommendation, prescription, purchase, supply, dispensing, or administration of our products.

- It is inappropriate for our employees to use any inducement or deception to gain access to, or obtain an appointment with, Healthcare Professionals (HCPs) / Other Healthcare Staff (OHS). The frequency and timing of appointments does not cause inconvenience for the HCP/OHS.

- Promotional activities to consumers, customers and HCPs/OHS must not include any healthcare advice or give the impression that healthcare advice is being provided.

- Two-way conversation with consumers, customers and HCPs/OHS to understand trends, perceptions, performance and market opportunities, both in person and online, is considered Market Research and not promotion. Market Research must follow **SOP-CHC-451:** *Consumer Healthcare Global Insights and Market Research SOP* (available on **CH Control Documents site**).

Our promotional information:

- Is consistent with locally approved labelling and prescribing information and the Claim Support Summary.

- Does not include un-approved uses, so-called “off label” promotion.

- Is clear, legible, up to date, accurate, fair, objective and balanced.

- Is capable of substantiation (verifiable).

- Is based on relevant evidence and sufficiently complete to enable the recipient to form their own opinion of the product.

Our promotional information is not:

- Misleading - by distortion, exaggeration, misrepresentation, undue emphasis, omission or in any other way.

- Knowingly offensive or disparaging.

- Disguised in any way (for example market research must not include promotional information).

ⓘ Promotional materials are not necessarily limited to the verbatim of the approved product information ("the label"). Promotional information respects the context and intent of information in the approved label and statements from the label must not be reproduced out of context.

ⓘ Disease/condition information proactively provided to HCPs/OHS must comply with these principles and the CH Code. If it is non-promotional disease or condition awareness information to be passed on to patients see **Section 7:** *Other non-promotional activities* or for a scientific engagement activity see **Section 11 / Appendix 1:** *Scientific Engagement*.

ⓘ The use of digital channels for promotion must comply with these principles, the CH Code and **POL-132175:** *Policy for Use of Digital Channels*.

2.2. Promotional information content

– Promotional material (printed and electronic) that includes benefit claims for the product or disease information must include the unique tracking code (ZINC code or similar) which allows tracking the date of approval.

- For digital channels targeted to audiences from more than one country, users from a single country must be able to access country-specific product information.

- Promotional material must include the required information as per local regulations or laws.

- Promotional materials must be balanced, not exaggerate benefits and be consistent with the approved label and claims.

- Promotional materials must not contain inappropriate use or representation of animals that could cause harm to GSK's reputation or that would likely result in a disproportionate negative response from consumers.

- It must not be stated that a GSK product has no side effects, no toxic hazards or no risks of addiction or dependency. The word 'safe' must not be used to describe effects on patients or consumers, and the words 'safely' or 'safer' must never be used to describe our products without qualification. An exemption is permitted for non-

prescription and consumer products for the use of the phrase "*Product X is considered safe and effective when used in accordance with its labelling*" when used in the context of reactive statements, press releases, and similar communications. Deviations from this phrase are not permitted and local Legal review and approval is required before releasing the statement.

- The word 'new' and equivalent terms are only used to describe our products (or uses, indications, presentations or formulations) that have been commercially available in the relevant country for less than 12 months. Promotional material that includes the word 'new' must be set to expire 12 months from initial approval date.

- Quotations, testimonials and artwork, including graphs, illustrations, photographs and tables, which are taken from publications and included in promotional material must:

  – Clearly indicate the precise source(s) of the artwork.

  – Be faithfully reproduced; except where adaptation or modification is required in order to comply with local laws, regulations or applicable industry codes, in which case it is clearly stated that the artwork has been adapted and/or modified.

  – Be authorised for use in accordance with relevant copyright law.

- Endorsements, quotations, testimonials and the like attributed to individuals or organisations such as government agencies, professional bodies, or independent agencies are:

  – Valid.

  – Current.

  – Verifiable (by citing published references or obtaining approval of the promotional material from the individual or organisation).

  – Consistent with the approved labelling information and approved by the same criteria as any promotional claim.

  – Follow requirements set by the organisation (for example written approval from the relevant association in advance of the final promotional material that contains or implies an endorsement by the organisation may be required).

- Promotional materials must be culturally appropriate for the relevant market. For purposes of this CH Code, "culturally appropriate" means compatibility with ethical, social, cultural and/or religious norms, standards, and/or feelings of local society, including ethnic or religious groups.

- The choice of images, artwork design and content of promotional material is to be considered against locally accepted standards and consistent with the reputation of GSKCH and its products.

- Information to support promotional claims is readily available to be provided in response to a request.

- **Promotional materials related to non-prescription products directed to consumers** must at minimum include the statement "Always read the label prior to use". Global Categories Medical may decide to define any additional warning /security risk information, which must be included for specific brands/products to achieve global alignment on patient safety position. The requirements of materials directed to HCPs/OHS are not required to be applied to materials directed to consumers.

- **Promotional materials directed to HCPs/OHS** on non-prescription products and prescription products must include at minimum the full actual Product Information Leaflet (PIL) or sections of the Summary of Product Characteristics (SPC) required by local laws and regulations (or direction to this information if this is permitted by local legal and regulatory requirements). On consumer products, full information needed for appropriate product use must be included. Global Categories Medical must define any additional warning /security risk information, which must be included for specific brands/products to achieve global alignment on patient safety position.

  The following requirements must be met for promotional materials directed to HCP/OHS:

  - Where published studies are referred to, clear references are included in the material.

  - The Global Claims Support Summary must always be followed, unless the local Summary of Product Characteristics is more restrictive. In cases where sections of local Summary of Product Characteristics are used in promotional copy, Summary of Product Characteristics needs to be mentioned in reference list.

  - Relevant information on the type of evidence available (e.g. double blind or open label clinical trial), side effects, contraindications, precautions, indications, relevant doses and/or methods of administration is included.

  - Patient numbers are included when expressing data as percentages.

- Where a clinical or scientific issue exists which has not been resolved in favour of one generally accepted view, the issue is treated in a balanced manner in line with the position approved by Medical.

- Comparisons between different products that provide information relative to a comparator (including a placebo) are based on relevant and comparable aspects of the products.

- There is a sound statistical basis for information, claims and comparisons in promotional material. Differences which do not reach statistical significance must not be used.

- Communication of efficacy and safety data includes the absolute rates, for example: 50% more subjects receiving Product X experienced improvement vs. placebo (improvement experienced by users of Product X was 15% vs. 10% for placebo).

- Claims for superior potency of a product (i.e. the product has a lower effective dose versus the competing product) are avoided unless they can be linked to a practical advantage such as a reduction in adverse reactions or cost of effective dosage.

- Price comparisons are made on the basis of equivalent pack sizes and product.

- Products must not be described as being "better" or "superior" without reference to the comparator. Comparative advertising can be used only if in line with local legal framework.

- The use of in-vitro laboratory or animal data to support claims of a health benefit is permitted only where the type of data are made clear and there is an established link between that data and the health benefit (e.g. a publicly available consensus by the scientific community and/or regulatory authorities).

2.3. Promotion to pregnant women

2.3.1. Principles

We must not promote medicine, cosmetic or nutritional products to pregnant women, unless efficacy or safety studies support the specific population use. Having long legacy or history of use must not be used to support the claims or population specific campaigns. A positive statement in the Summary of Product Characteristics / Global Data Sheet / Product Information File (SPC/GDS/PIF) is needed to indicate the product use in

pregnancy, which will reflect the clinical efficacy and safety data to support to the claim or indication.

Promotion must reflect any warning statements on the SPC or labelling concerning use during pregnancy.

2.3.2. Proactive promotion to pregnant women

- Materials must focus on the advice to take prescription medicines or non-prescription products in pregnancy only when absolutely necessary and to seek professional advice before taking the product.
- Promotion must not convey messages that it is usual for pregnant women to take prescription medicines, non-prescription products or consumer products in pregnancy and materials must raise awareness of the risks of taking medicines through pregnancy.
- All promotional materials promoting use in pregnancy must be used only if a proper assessment is done to evaluate if the expected benefit to the mother is thought to be greater than the risk to the fetus, and all drugs must be avoided if possible during the first trimester. Prescription products and non-prescription products which have been extensively used in pregnancy and appear to be usually safe must be prescribed or recommended in the smallest effective dose.
- All promotional material promoting use in pregnancy must include a general warning message appropriate to the medium being used (e.g. print, television, radio). An example of appropriate general messaging is as follows: “Medicines can affect the unborn baby. Always talk to your doctor or pharmacist before taking any medicine in pregnancy”.

2.3.3. Proactive promotion to HCP/OHS about pregnant population

- Promotion must never state or imply that the advertised prescription, non-prescription product, or any consumer product cannot harm the developing fetus.
- All promotional materials for products must include the statement: “Care must be taken when prescribing in pregnancy as medicines can cross the placenta and may affect the fetus.”
- When there is no clear indication of use in pregnancy, use of images of pregnant women is not appropriate.

- All information below, related to the product, from the SPC/GDS/CTD/PIF must be mentioned in promotions:
    - Facts on human experience and conclusions from preclinical toxicity studies which are of relevance for the assessment of risks associated with exposure during pregnancy.
    - Recommendations must be clear on the use of a medicinal product at different times during pregnancy in respect of gestation.
    - Recommendations which may be needed to manage situations of an inadvertent exposure must be included, where relevant.

ⓘ Promotional material produced by categories for distribution to LOCs follow **SP1910:** *Claim and Copy Approval* and **WI1484:** *Claim & Copy Approval.*

3. Promotion to consumers

All promotional materials (e.g., product Facebook page, flyers, TV commercials etc.) targeted to consumers must comply with **Section 2.1:** *Principles for promotion* and **Section 2.2:** *Promotional information* and **Section 2.3:** *Promotion to pregnant women*.

See also **Section 7.2** for disease awareness to the general public.

3.1. General principles

Promotional activities directed to the general public (also referred to as 'consumer promotions') include initiatives intended to promote sales or trial of a product. They generally involve providing additional benefits, usually on a temporary basis. Examples include advertising (via all media), product related external communications (for example product or claim related press releases), discount pricing, coupons, prize promotions, gifts with purchase, 'two for the price of one'.

All consumer promotions must be conducted in compliance with applicable local regulations and in a way that promotes the responsible use of our products.

Stricter rules apply when promoting non-prescription products to consumers compared to promoting consumer products.

GSK CH sales representatives and expert marketing staff can promote directly to consumers using materials and messages approved via the CCAT process (ZINC), sample to consumers or distribute coupons. During these promotional activities to

consumers GSK CH staff must not provide any healthcare advice or give the impression that healthcare advice is being provided.

3.2. Internal authorisation

All new consumer promotional materials will be approved via the CCAT process (ZINC) in compliance with **SP1910**: *Claim and Copy Approval* and **WI1484**: *Claim & Copy Approval*.

3.3. Price and volume promotions of non-prescription products and consumer products to consumers

Price Promotions: Typically price promotions are managed through retailers to pass on to consumers or directly to consumers. Price promotions of non-prescription and consumer products are permitted and may be presented in the form of money-off coupons, vouchers, loyalty cards and discount pricing. The value of the price promotion may not exceed 50% of the manufacturer's recommended retail price unless with the permission of a Vice President in Legal Operations. Price promotions of prescription products to consumers are only permitted where local regulations allow.

Principles of Price Promotions

- **Must be in compliance with Competition Law standards**
- **Money off must not be excessive (no more than 50% of a product price).**

Volume Promotions of non-prescription products and consumer products to consumers: Typically these promotions are managed through the retailer. Volume sales promotions include offers such as 'two for the price of one'. Consumers must still have the choice of buying a single product.

Non-prescription products: There are important ethical and safety concerns associated with this type of promotion when dealing with non-prescription products. The promotion must not encourage overuse of the non-prescription medicine by a consumer.

Volume promotions of prescription products to consumers are not permitted.

3.4. Gift with purchase

Gifts with purchase are allowed, however the gift must be of lower value to the consumer than the cost of a product or set of products, and in accordance with local laws and regulations.

Principles for gifts with purchase

- The gift must be of lower value compared to the price of the product or set of products (both the actual and perceived value) so as not to encourage purchase of the product to get the gift.
- Gifts with purchase of non-prescription products and consumer products are allowed when in accordance with local law.
- Consumers must not be required to purchase excessive amounts of a product in order to obtain the gift.
- For non-prescription products,
    - the gift must not be targeted to children nor be likely to result in the consumer needing to use more of the medicine.
    - The gift must be related to the use of the non-prescription medicine (e.g. hygienic tissues added to Otrivin, cup added to pack of Panadol Cold & Flu).
- The promotion must not encourage overuse of the non-prescription product by a consumer.
- Gifts with purchase of prescription products are not permitted.

3.5. Promotional aids

Promotional Aids (sometimes called Brand Reminders) are minimal value promotional items, that carry company or product branding or product claims and are given to consumers. They are provided free and are not dependent on product purchase. Examples include T-shirts, pens, cups, coasters, note pads and mouse mats. They do not have to be related to the use of the product. Promotional Aids are only used for non-prescription products and consumer products. Promotional Aids must always be

approved via the CCAT process (ZINC), contain the product brand or GSK logo and may contain product claims.

Promotional aids must not be used for prescription products.

See **Section 5.11** on Promotional aids to HCPs or OHS.

3.6. Promotions with prizes

The use of competitions, quizzes, raffles and suchlike and the giving of prizes is permitted for non-prescription products and consumer products. The use of sweepstakes, competitions, quizzes, raffles and suchlike and the giving of prizes is prohibited for prescription products. The use of competitions, quizzes, raffles and suchlike and the giving of prizes in relation to HCPs and OHS is not permitted.

Seek legal, medical and quality advice to ensure local legal and safety requirements are fulfilled before developing such programmes.

3.7. Testing and sampling

- Testing and sampling activities allow consumers to be familiarised with a product or its use free of charge. These activities can be carried out at public events, in stores, or through direct mailing where permitted by local laws, regulations and industry codes. Sampling of prescription products directly to consumers is not permitted.

- Non-prescription products can be sampled to consumers if permitted by local laws, regulations or industry code. The sample/tester size must be no larger than the smallest commercially available size. Labelling language such as "product sample – not for resale" or similar language must be added to the sample, where local regulations require it.

- For consumer products, the sample size may be larger than the smallest commercially available size. The requirement to include on the label "product sample – not for resale" or similar language must be determined based on local risk assessment including an assessment under local competition law.

- Samples to consumers must ensure that the distribution requirements, including storage requirements, are managed (e.g. appropriate refrigeration if required, security of samples, inventory management) and there must be a process to track samples distributed to enable recall and audit in line with the local law. It is recommended to

allow the longer of at least 6 months shelf life or shelf life that is required by local laws and regulations.

4. Promotion to trade customers (not consumers)

While promoting to customers, the anti-bribery and competition law risks associated with the promotional activities must be understood and promotions must be conducted pursuant to the **Pricing Risk Governance and Compliance Framework**.

4.1. Promotion to customers (e.g. retail and pharmacies)

Promotional materials, which include brand claims and disease area copy (e.g. trade presentations), targeted to retail customers must comply with **Section 2.1:** *Principles for promotion* and **Section 2.2:** *Promotional information* and must be approved via the CCAT process (ZINC) in compliance with **SP1910:** *Claim and Copy Approval* and **WI1484:** *Claim & Copy Approval*.

We promote in a country only after any necessary authorisations for the use and conditions for use have been granted in that country. In preparation for product launches, certain promotional activities with customers can be planned. Consult local Regulatory, Legal, and Medical on what can be discussed with retail customers and at what stage of the regulatory approval process, including "coming soon" or new product promotions.

ⓘ Relationships with a pharmacist can be in the capacity of a customer (owner operated pharmacy where GSKCH sells product to the pharmacy) or an HCP (GSKCH details about our products to the pharmacist). Sales representatives can interact with the pharmacist in both capacities as a customer and an HCP. Examples of each would include the following:

- HCP Capacity – Product and disease area science presentation, dosing, indications and contraindications
- Customer Capacity – Product pricing, volume discounts, consumer advertising support, shelf placement recommendation

When interacting in the capacity of a customer this section is followed, when interacting in the capacity of an HCP **Section 5**: *Promotion to HCPs/OHS* must be followed.

ⓘ Presentations and detailing to owner/operator Pharmacists are considered promotion and must be treated as an HCP versus a customer. For other trade related presentations and price negotiations, see **Section 4.2:** *Trade investment policy*.

4.2. Trade investment policy

- Discounts, rebates, free of charge goods and other commercial terms relating to price or margin are assessed using the **Pricing Risk Governance and Compliance Framework** and applicable laws and regulations.

- Particular care is taken when the purchasing customer is also an HCP/OHS, to ensure that the commercial terms would not unduly influence them to prescribe, dispense or recommend a product inappropriately, or to act in a way that is not in the best interest of patients or the relevant healthcare system. Pricing, discounts or rebates must not be designed to favour individual pharmacies or retailers without objective justification, but must be offered to the pharmacists consistently based on objective criteria (i.e. different discounts are given to customers of substantially different sizes or to pharmacy chains compared to private pharmacies).

- Business units and LOCs ensure that their supply arrangements comply with the following requirements:

    - A pricing risk assessment must be performed per the **Pricing Risk Governance and Compliance Framework** and there must be a documented assessment per the framework that governs the levels of pricing, discounts, rebates, free goods and other commercial terms. This framework contains the rationale for commercial terms and is reviewed by Finance and Legal.

    - Commercial terms offered are documented in writing to ensure transparency. The **Pricing Risk Governance and Compliance Framework** specifies the documents required.

    - Any discount, rebate or other payment is made via an approved financial method (e.g. invoice, bank transfer or cheque) and does not take the form of cash or other cash equivalent. Discounts, rebates and other payments are accurately and appropriately recorded in our books and records.

    - Any schemes which enable HCPs/OHS to obtain personal benefits in relation to the purchase of products are unacceptable even if they are presented as alternatives to commercial terms.

- Trade programmes are intended to drive share growth and enhance the equity of our products through fair and equitable investment and partnership with GSKCH customers. Any funding to customers must be for promotional activity in the retail environment, clearly documented and agreed with customer. All funding must be provided for the specific activities for which the funding is being used and be approved within the **Pricing Risk Governance and Compliance Framework**.

- Examples of Trade Fund classifications include but may not be limited to:

    - Development Funds (DF) - Trade funds assigned to each customer in order to run consumer-oriented programmes designed to raise brand awareness. In most cases a customer accrues funding based on a percentage of sales to that customer with rates determined during business planning process, but there are instances where the funding is fixed based on an activity. Examples of programmes funded include feature ads in customer circulars, flyers, in-store coupons, etc.

    - Incremental Funds (IF) - Trade funds intended for investment in specific objectives driven by needs of the business or relevant market drivers. These funds are used to disproportionately invest in accelerated growth opportunities, or where there is other identified and business aligned needs at that time.

    - Shopper Marketing Funds (SMF) - Designed to promote and build brand equity through consumer and shopper based insights, rather than promote sales through price discounts. Examples would include consumer wellness programmes, in-store TV spots or joint promotions.

    - Markdowns and Un Saleable Provisions - These funds are used to support retail price reductions in an effort to liquidate inventory intended to minimise the return of discontinued merchandise. Care must be taken when price is marked down to avoid risk of predatory pricing risks under relevant competition laws especially when GSK has a dominant market position. GSK Legal must always be consulted in relation to proposed markdowns. The Markdown funds must include unsalable returns provision.

- Expenses considered trade funds include but may not be limited to:

    - All discounts (off and on invoice) such as: feature ad, feature display, customised packaging, in-store events, customer specific couponing, customer specific rebate, Pharmacy programme, merchandising programme, payment to 3rd parties supporting promotion activities, cooperative advertising, etc.

- Trade fund budgets must be approved as per the **Pricing Risk Governance and Compliance Framework**.

- It is the responsibility of the Account Manager and Sales Director to ensure trade funding is managed within policy and that neither the total nor individual commitments exceeds allocated budgets.

- Promotional programmes must be open, transparent and clearly documented; clearly describing expected performance, methods to prove performance and value received by GSKCH. Appropriate documentation varies by channel and customer type. Examples include, but are not limited to: channel-wide schemes communicated in a brochure or selling aid, e-mail exchanges between account managers and buyers, trade fund agreements and contracts.

- Off-invoice discounts must be based on value received by GSKCH in exchange for the discount. Actual off-invoice amounts must be consistent with the original plan and existing documentation.

- Trade investments must be properly accrued and posted monthly to the company's financial statements.

- Settlement of Trade Fund claims must be processed as they occur to ensure accurate information and accrual tracking.

- Proof of performance / activity is required prior to the settling of a claim and will vary depending upon the type of claim.

4.3. Promotional events

- Depending on the category of the customer, different promotional events may take place. These could be designed to drive product awareness (i.e. new product launch event) or enhance category / commercial knowledge. The programme of the event must make clear the intent and any hospitality provided must be minimal and incidental. No recreational activities are permitted.

- The events may take place in the customer's premises or in a proper venue, in such case **STD_404715:** *GSK Standard on Meetings and Catering* must be adhered to.

- In cases, that external speakers / presenters are contracted for the event ABAC framework and **SOP_344448**: *Engaging with Healthcare Professionals (HCPs) to Provide Services* must be adhered to as required.

- All promotional materials created for / used in these events must be approved via the CCAT process (ZINC). The information shared must be consistent with the

Competition Law and *Write Right guidelines* as well as **SOP-191843: SOP-GSK-301** *External and internal communications activities on behalf of GSK*.

- Where the promotional events are agreed to group purchase organisations (for example organisation of pharmacy owners), the invitation must be extended to all their members, GSK must not selectively invite certain members only.

4.4. Samples to Customers

- Samples of non-prescription products and consumer products can be given to customers (e.g. mass market, chain pharmacy, e-commerce (Amazon), discounters, wholesalers/distributors or individual pharmacy), as part of product listing, trade promotional activities, in order to help customers understand our product appearance, pack size for placement, etc. All pack sizes can be provided to customers however they must be limited to small quantities (generally less than 5 units per item). It is recommended to allow the longer of at least 6 months shelf life or shelf life that is required by local laws and regulations. Prescription products cannot be sampled to customers unless they are provided as part of a detailing session to pharmacists with prescribing authority when they are acting in the capacity of an HCP. The local law, regulations and industry code requirements must be followed when sampling to pharmacists and other HCPs.

- If products are sampled to customers in preparation for launch, prior to sampling the product GSK Pharmacovigilance and Safety functions (named safety contact, customer service) must be informed.

4.5. Promotional Aids and Prizes to Customers

- Promotional Aids (sometimes called Brand Reminders) are minimal value promotional items that carry company or product branding or product claims and are given to customers or to their staff. They are provided free and are not dependent on product purchase. Examples include T-shirts, pens, cups, coasters, note pads and mouse mats. They do not have to be related to the use of the product. Promotional Aids are only used for non-prescription products and consumer products. Promotional Aids must always be approved via the CCAT process (ZINC), contain the product brand or GSK logo and may contain product claims.

- The use of competitions, quizzes, raffles and suchlike and the giving of prizes is permitted for non-prescription products and consumer products. The use of sweepstakes, competitions, quizzes, raffles and suchlike and the giving of prizes is

prohibited for prescription products. The use of competitions, quizzes, raffles and suchlike and the giving of prizes in relation to pharmacists is permitted only with explicit legal approval.

Seek legal, medical and quality advice to ensure local legal and safety requirements are fulfilled before developing such programmes.

5. Promotion to HCPs/ OHS

5.1. All promotional meetings

The purpose of our promotional meetings is to proactively provide information about our products and/or the diseases/conditions for which they would be used. Meetings (including third party medical education events) that we influence (e.g. by suggesting or providing content or by selecting/recommending speakers) are GSK promotional meetings and must follow this CH Code.

Promotional meetings and materials used in these meetings must follow the below criteria:

- All promotional materials relating to approved products (e.g., HCP detailing aids) targeted to HCPs/OHS must comply with **Section 2.1:** *Principles for promotion* and **Section 2.2:** *Promotional information* and must be approved via the CCAT process (ZINC) in compliance with **SP1910:** *Claim and Copy Approval* and **WI1484:** *Claim & Copy Approval*.

- Where hospitality is provided at a meeting, it is incidental. Refer to section 6 for further details regarding hospitality and travel expenses to HCPs/OHS. The same principles must be followed when expert sales teams conduct detailing sessions to HCPs/OHS, sometimes referred to as 'Lunch and Learn' or 'In Service' sessions.

- Promotional meetings only occur when we are able to ensure that the meeting adheres to the requirements of this section and other relevant requirements of this CH Code, including that the data presented and materials provided promote only approved uses of our products.

- For any promotional meeting for HCPs/OHS, it must be the content of the programme that attracts a delegate to attend.

- Commercial staff (usually Expert Marketing or Expert Sales) are responsible for promotional meeting organisation and management.

- The intent of the promotional meeting is clearly disclosed to the participants.

- Promotional meetings include GSK *stand-alone meetings*, and GSK *sponsored satellite symposia* at scientific/medical congresses, speaker programmes and promotional webinars (see also **written standard on webinars**).

- Presentations in the core programme (i.e. not stand alone meetings or satellite symposia) of medical congresses or meetings for Independent Medical Education are not promotion (see **Section 11** / **Appendix 1:** *Scientific Engagement*).

- Presentations and detailing to owner/operator Pharmacists are considered promotion and must be treated as an HCP versus a customer. For other trade related presentations and price negotiations, see **Section 4.2:** *Trade investment policy*.

5.2. Meeting Material (including content of presentations)

All promotional materials must comply with **Section 2.1:** *Principles for promotion* and **Section 2.2:** *Promotional information* and must be approved via the CCAT process (ZINC) in compliance with **SP1910**: *Claim and Copy Approval* and **WI1484**: Claim & *Copy Approval*.

- The promotional materials for non-prescription products and prescription products must include abbreviated or full Patient Information Leaflet (or direction to this information if this is permitted by local law or regulation).

- GSK involvement is disclosed in communications relating to the meeting and in any published proceedings. The declaration of GSK's role is clearly visible.

- Materials are reviewed and approved for compliance against the local requirements of the country in which the meeting is held. Where specific HCPs/OHS are directly invited by GSK from outside the country, where the meeting is being held (or the meeting, or a recording of the meeting, is targeted to them), the material must be approved by the relevant market Medical Head (e.g., the material is approved as consistent with the product label of the HCPs/OHS home country and disclose the list of countries where the product is authorised and not authorised).

- A GSK hosted meeting must always held in a country where the relevant product or use is authorised. If the expected attendees are from outside the venue country and from countries where the product is not authorised, materials must include the list of countries that the product is authorised.

- GSK may participate in an international congress held in a country where the relevant product or use is authorised or is not authorised. If the expected attendees are from

outside the venue country and from countries where the product is not authorised, materials must include the list of countries that the product is authorised.

5.3. GSK speakers and attendees

Appropriately trained Expert Marketing or Expert Sales staff are responsible for promotional presentation of our products and/or their disease condition areas at promotional meetings. Medical Affairs/R&D staff may get involved in justified cases on a non-frequent basis, where clear benefit to patient health and safety can be justified. Such events have to be infrequent. Medical Affairs/R&D staff should independently decide which promotional meetings/events to attend.

Our staff that speak, attend, or participate in meetings are transparent about their employment by GSK.

5.4. External speakers

- *HCPs who are Government Officials*: We do not pay HCPs/OHS who are considered Government Officials to speak on any topic unless there is an approved exception by a CET member or delegate. We also do not pay for travel, accommodation or meals. Reference **STD_455141 (1.0)** *Anti-Bribery and Corruption Standard* for more information.

- *HCPs/OHS who are not Government Officials*: We do not pay HCPs/OHS to speak on our behalf to other HCPs/OHS about our prescription products and/or their disease or condition areas. We can pay HCPs/OHS to speak on our behalf for our non-prescription products and consumer products. These HCP/OHS speaker engagements must be on a fee for service basis. There will be no unpaid speaker engagements. Refer to **Consumer Healthcare Guidance on Engaging HCPs** (see **Section 6:** *General Requirements for interactions with HCPs/OHS* and **Appendix 3:** *Consumer Healthcare Promotional aids and Items of Medical/Educational Utility (IMUs) for individual HCPs*) for details on the types of engagement and scenarios when Consumer Healthcare can engage HCPs and OHS and the governance process. Reference **SOP_344448**: *Engaging with Healthcare Professionals (HCPs) to Provide Services* for requirements on engaging HCPs/OHS to provide service.

- Reimbursable travel expenses must be outlined in the contract. A GSK preferred travel agency, where available, must be utilised for travel arrangements and the expenses are to be paid to the agency upon presentation of the original invoices. If a

preferred travel agency is not available, reimbursement is made to the HCP/OHS upon presentation of the original invoice.

- It must be disclosed verbally at the event that the speaker is paid for by GSK Consumer Healthcare and not the GSK Pharmaceutical business, and the programme is about non-prescription products or consumer products.

- We require the speaker to make an appropriate and clear verbal disclosure at the beginning of each speaking engagement to describe any paid service provided to GSK Consumer Healthcare during the preceding 12 month period – for example:

  "I am a paid consultant/investigator for GSK. GSK Consumer Healthcare has paid for this speaking engagement and reimbursed my travel costs for this engagement.

- The materials must clearly disclose GSK Consumer Healthcare involvement. Only stating "GSK" is not adequate.

5.5. GSK sponsored satellite symposia

Satellite symposia may be promotional – covered by Commercial budget or scientific – covered by Medical Affairs budget. Commercial is accountable for promotional satellite symposia and the content and Medical Affairs has accountability for the scientific satellite symposia and the content.

- The scientific and medical content of a satellite symposium and the appropriateness of the speaker faculty are approved by the relevant Country Medical Affairs Leader or designee for the country in which the event occurs. Logistical arrangements may be implemented by non-Medical Affairs teams or a contracted vendor.

5.6. Commercial booths at meetings

- Commercial booths are staffed by commercial staff trained to discuss our products with delegates consistent with labelling information and in accordance with relevant promotional rules.

- Competitions (including raffles and lotteries), gifts, recreation and entertainment are not permitted, (basic refreshments such as tea and coffee are permitted). Non-competitive quizzes that relate to scientific/medical knowledge or skill in the relevant disease area are permitted.

ⓘ If an HCP/OHS asks an off-label question or asks a question that requires a written response, the question is captured and submitted as a Medical Information enquiry (see **SOP_209087**: **SOP-CHC-409**: *Consumer Healthcare Medical Governance* and **WI1435** *Management of Medical Information Enquiries).*

5.7. Detailing HCP/OHS

Also see **Section 2.1:** *Principles for promotion* and **Section 2.2:** *Promotional information* for additional information.

The following applies to sales representatives and others who detail our products to HCPs/OHS.

- Sales representatives and Expert Marketing staff are given adequate training and have sufficient scientific knowledge to enable them to provide relevant and accurate information about the products they detail.

- Sales representatives and Expert Marketing staff ensure they do not mislead as to their identity, role or the company they represent.

- All detailing materials must be approved through the local claims and copy approval process (including medical papers or extracts of any articles, even if these are published in peer reviewed journals). Materials relating to products or indications that do not have appropriate authorisation are not referred to or distributed by sales representatives or Expert Marketing staff.

- Sales representatives and Expert Marketing staff must not solicit any requests for off-label information on our products.

- Medical Information is scientific and clinical information related to usage, efficacy and safety of any GSK CH product whether on label or off label, which is delivered in response to unsolicited enquiries from Healthcare Professionals, including payers and managed healthcare organizations, and consumers. Sales representatives and Expert Marketing staff receiving unsolicited requests for off-label medical information, or those requiring a written response, forward such requests to the Medical Information function (see **SOP_209087**: **SOP-CHC-409**: *Consumer Healthcare Medical Governance* and **WI1435** *Management of Medical Information Enquiries).* Responses to medical information requests are sent directly to the HCP/OHS requesting the information.

- Sales representatives and Expert Marketing staff supply current, approved labelling/prescribing information if requested by an HCP/OHS.

- Sales representatives and Expert Marketing staff must not:
    - Deliver Medical Information written responses to HCPs/OHS.
    - Receive a copy of the Medical Information responses sent to HCPs/OHS; they can receive notification that their request has been answered.
    - Request Medical Information responses for their own use.

5.8. Medical Affairs/R&D involvement in promotional activities

- R&D/Medical Affairs staff does not accompany sales representatives and Expert Marketing staff in the field to meet in 1:1 type interactions with HCPs/OHS unless on specific occasion, where there is an exception approved by the regional/area Medical Affairs Leader or designee.
- R&D/Medical Affairs staff does not discuss clinical research or scientific engagement (see **Section 11**) activities with HCPs/OHS in the presence of a sales representative or Expert Marketing Staff.
- When proactively presenting data or information on our products and/or the associated disease areas or conditions, Medical Affairs/R&D staff is acting in promotional capacity and **STD-GSK-415**: *Standards for External Interactions by Medical Affairs and R&D staff* applies.

5.9. Samples to HCPs and OHS to familiarise patients / consumers

- Samples are products given to HCPs/OHS at their office, free of charge to familiarise themselves with a particular product and its use in patients, and/or to facilitate patient experience with the product.
- Product samples can be given to HCPs / OHS authorised to prescribe, recommend or supply that product, provided this meets local laws, regulations, applicable industry codes and any global, regional or local GSK requirements for specific products. For guidance on sampling to medical and dental students see **Section 5.12:** *Promoting to medical and dental students*.
- Local requirements, accountabilities, processes and governance of samples to HCPs are to be documented in a local SOP or guidance document which includes:
    - The rationale for providing samples.

- Acceptable volumes.
- Duration of sample distribution.
- Distribution requirements including storage requirements where needed (e.g. appropriate refrigeration if required, security of samples, inventory management).
- Labelling for prescription product samples must contain "free product sample – not for resale" or words to that effect and accompanied by approved product information.
- Labelling for non-prescription products must follow local regulations. "free product sample – not for resale" or similar language must be added to the sample as required by local regulations.
- A country can adopt a less stringent labelling standard for consumer products based on local regulations and on the risk of potential product diversion (potential product sale in the grey market).
- Samples of prescription products and non-prescription products to HCPs / OHS must not be larger than the smallest pack size that is marketed in the country.
- Consumer product samples can be larger pack sizes than the smallest pack size marketed in the country, based on market needs and on assessment under local competition law.
- Processes to track sample distributions, enable recall and audit in line with the local law.
- Guidance for sample quantities and monitoring to ensure the quantity is not excessive.
- Any specific local legal requirements (including any modifications to the global requirements in this CH Code) to ensure compliance with local regulation.

- Samples are not provided for clinical studies or compassionate use or to address issues of patient access to our product. Separate processes are in place for product for clinical trials or product donations and must be followed.
- The Consumer Healthcare Local Operating Company maintains an approved list of products and presentations which can be offered as samples (pack size for prescription products and non-prescription medicines may not be larger than the smallest presentation available within that country, consumer products may be larger). It is recommended to allow the longer of at least 6 months shelf life or shelf life that is required by local laws and regulations.

ⓘ Within Europe, quantities of samples of prescription products and non-prescription medicines are limited to four samples per year per HCP/OHS for a restricted two year period post-launch. Each LOC within Europe determines the launch date (product availability date to trade) that will trigger the start of this two year sampling 'window' for each new product or indication.

5.10. Samples to HCPs and OHS at Congresses and Conferences

Sampling to HCPs and OHS at conferences and congresses is primarily for them to try our products (product familiarisation) and is unlike sampling in HCP offices, where the intent is that the HCP/OHS further distribute to patients / consumers. Sampling to HCPs/OHS at congresses and conferences must follow the following principles:

- Non-prescription products (as per local regulations and limits) and consumer products can be sampled to HCPs/OHS at congresses and conferences. This is for HCPs/OHS to familiarise themselves with our products but not to distribute to patients / consumers and so must be in limited quantities – typically one or two items of each sampled product per conference. GSK accounts for the fact that individual HCPs/OHS might attend different local and regional congresses in the same year and therefore get more than one or two products. This must be considered when planning sampling at conferences.

- Prescription medicines cannot be sampled to HCPs/OHS at congresses and conferences.

- Samples of non-prescription products must be limited to the smallest pack size. Labelling language such as "product sample – not for resale" or similar language must be added to the sample where local regulations require it.

- Consumer product (toothpaste, skin health products, nutritionals) samples can be larger size packs. The requirement to include on the label "product sample – not for resale" or similar language must be determined based on local risk assessment including an assessment under local competition law.

- The value of the samples given must be modest. The country local limits established on brand reminders to HCPs/OHS must be followed.

- The sampling plan and items to be sampled to HCPs/OHS at a conference must be approved by the country Medical Director. It is recommended to allow the longer of at least 6 months shelf life or shelf life that is required by local laws and regulations.

ⓘ Local/EU legislation imposes a limit to number of medicinal product packs which can be given to HCPs/OHS. Impacted LOC staff (Medical, Marketing, Expert Marketing and Sales teams) have to be aware of this limit and ensure the allowance is not exceeded.

ⓘ Quality, Logistics and Commercial staff involved in the sampling process must ensure that the distribution requirements for samples including storage requirements are managed (e.g. appropriate refrigeration if required, security, inventory management) and have a process to track sample distributed to enable recall and audit in line with the local law. LOCs required to track samples in this capacity must track the product sample, the total number of each sample distributed, and the batch number. It is not required to track samples given to HCPs/OHS at conventions for familiarization at an individual HCP level for transfer of value transparency reporting purposes (for example European Federation of Pharmaceutical Industry Association – EFPIA – reporting).

5.11. Promotional aids

- Promotional aids (sometimes called Brand Reminders) can be given to HCPs/OHS provided they are permitted by local laws, regulations and codes; they are of minimal value (to be defined and documented locally), relevant to the professional activities of the recipient and provided on an infrequent basis.
- They do not need to be product related.
- Excludes gifts of personal benefit and must not be given frequently to subsidise routine HCPs/OHS practice costs.
- Similar items may be given to HCPs/OHS in an office setting and at conferences. Consult to Appendix 3 for prescription products as different rules apply.
- Promotional aids may carry product branding, company branding and product claims.
- Refer to the Guidance on Consumer Healthcare Promotional aids and Items of Medical/Educational Utility (IMUs) for individual HCPs in **Appendix 3**.
- Refer to **Section 3.5** for guidance on consumer Promotional aids.

ⓘ Where permissible by local law, single use plastic or paper bags, which may be branded (but not branded for prescription products), may be used at exhibit stands in order for delegates to carry away approved items from the exhibit stand. For GSK non-prescription products and consumer products, the product and company branding

and product claim may be used and visible, where permitted by local regulations and/or codes.

- In the USA and Canada promotional aids to HCPs/OHS are not permitted.
- R&D/Medical Affairs staff are not permitted to provide promotional aids to HCPs/OHS.

5.12. Promoting to medical and dental students

Medical, dental and other healthcare related students (e.g., dental hygienist and nursing students) are future HCPs/OHS. If they are authorised to prescribe or recommend they are considered HCPs/OHS and the principles for promoting to HCPs/OHS apply. If not, the students are treated as consumers and the principles for promoting to consumers apply.

6. General requirements for interactions with HCPs/OHS

6.1. Engagement of HCPs and OHS to provide services

- We can engage HCPs/OHS for services such as creating expert marketing material, consulting, public relations activities, advisory boards, experts to support prescription product registration, for regulatory support, and consulting services. HCPs are considered high risk third parties as per our GSK ABAC policy and the HCP Engagement process must be followed. **SOP_344448**: *Engaging with Healthcare Professionals (HCPs) to Provide Services* is followed. Also refer to the *Medical Governance in Consumer Healthcare for Engagements with External Experts*.

- Government Officials: We do not pay HCPs/OHS who are considered Government Officials to speak on any topic, unless there is an approved exception by a CET member or delegate. We also do not pay for travel, accommodation or meals (see **STD_455141:** *Anti-Bribery and Corruption Standard*).

- Speaker Engagements: We do not pay HCPs/OHS to speak about our prescription products or associated diseases. We can pay HCPs/OHS to speak about our non-prescription products and consumer products. Refer to Appendix 3 of the **Consumer Healthcare Guidance on Engaging HCPs** for details on the types of engagement and scenarios when Consumer Healthcare can engage HCPs and OHS and the governance process. The decision about when GSK can pay HCPs/OHS to speak about non-prescription products will be determined by the regulatory status of the product in the country where the HCP/OHS engagement occurs. For example, paid

engagements may include HCPs speaking about toothpaste brands and diseases related to these products to other prescribers (such as HCPs/OHS who are dentists but who also have lawful prescribing authority in that country). Such HCP engagements and payments can be made by the GSK Consumer Healthcare business only.

- Information provided to an HCP/OHS is limited to the information that is necessary to provide the services. In cases when confidential information has to be shared with HCPs/OHSs a Confidentiality Agreement has to be completed. Business Owner who is engaging HCP/OHS is responsible for the Confidentiality Agreement which is subject to the LOC/Area Legal Counsel approval before the data is shared.

- Payments follow the principle of fair market value (FMV). FMV rates are based on applicable documented rates/fee schedules aligned across all GSK businesses in any given market. **FMV rates are established by country** and are published and utilised across all GSK business (Pharma, Vaccines, and Consumer Healthcare) consistently and must be followed. When FMV rates specific to CH activities (HCPs/OHS engagement for promotional activities, such as TV commercials, digital etc.) are not covered on the global FMV schedule, then the FMV for such activities must be set by the Country Medical Affairs Leader and the local Pharma Medical Director, in the country where the HCP/OHS is domiciled, must be informed. The following factors are considered:

  - ABAC policy

  - Local industry regulator guidelines.

  - Local Medical Association or similar, or industry guidelines.

  - Categorisation of the HCP/OHS (e.g. Doctor – Professor, lecturer, GP, nurse, pharmacist).

  - The justification for the local fee schedule is documented and locally approved by the appropriate governance body (e.g. Risk Management and Compliance Board (RMCB)). Any exception to the fee schedule is reviewed and approved by the Regional Medical Affairs Lead.

- It is appropriate to compensate an HCP/OHS for travel time only when the travel is long distance (more than five hours), when the travel is required to complete the service and if the HCP/OHS is not already travelling for another purpose.

- Business class or premium economy air travel may be provided for HCPs/OHS engaged to provide a service, where the total flying time one way is more than five hours. Economy class travel can be reimbursed for air travel time less than five hours. Travel by train/bus may be business or first class. We may also reimburse

reasonable expenses incurred by the HCP/OHS in the provision of the services, subject to submission of receipts.

- If compensation for travel time is offered, a clear methodology for the calculation is documented and applied consistently.

ⓘ In countries where compensation for travel time is permitted, it is not automatically offered as part of the engagement. Compensation for travel time is calculated as a separate component on an hourly basis, and added to the hours engaged for the actual activity. If there is no set fee schedule involving compensation for travel time, the fee is not more than 50% of the fair market value hourly rate multiplied by the number of hours capped at one day (8 hours) per journey (outbound and return count as two journeys).

ⓘ We may pay for authorship of promotional articles or plenary congress presentations for non-prescription products and consumer products only. The promotional intent of the article or presentation as well as GSK involvement has to be disclosed. The contract with the HCP/OHS must include the statement that the principles of this CH Code must be followed.

6.1.1. Annual cap

- Each country in which GSK operates sets an annual maximum financial limit (cap) on the fees for service that can be paid directly to an individual HCP/OHS within their country. This cap applies to the total cumulative fees received by the HCP/OHS from any part of GSK (GSK Annual cap is the sum of HCP/HCO annual payments made by GSK Pharma, Consumer Healthcare, Vaccines and ViiV where applicable. All GSK businesses need to make sure that the payments to HCP/HCO are coordinated during the year not to exceed the Annual cap.)

    - The cap covers payments made to the HCP/OHS such as the fee for service and compensation for travel time. Unless required by local laws or regulations, the cap excludes subsistence, travel costs (e.g. airfare) and accommodation. Payments for clinical trials or activities related to clinical trials are excluded. Exceptions can be approved by the Regional Medical Affairs Lead in consultation with the Country Medical Affairs Leader.

ⓘ In the USA, currently the annual cap that has been set is $100,000 per calendar year.

ⓘ Outside the USA, the maximum cap that an LOC can set is the upper limit of fair market value hourly fee x 20 days x 8 hours per day.

6.1.2. Records and disclosures

Each LOC keeps detailed records of the fees paid, expenses reimbursed and transfers of value, in respect of services provided by the HCP/OHS in their country. These records are available for disclosure if required.

6.2. Meeting venues

GSK hosted meetings and meetings where we provide financial support (see **Section 6.4:** *Funding of third party scientific/medical congresses and other third party meetings*):

- Are not held at locations which could reasonably be perceived as lavish or extravagant for a business meeting or conference, or at venues which are recognised for their entertainment, sports or leisure facilities. A venue, such as a sports stadium, with conference facilities may be a justifiable venue where the meeting does not coincide with a sporting event.

- Provide safe accommodation where the risks to the security of attendees can be minimised. Corporate Security & Investigations are consulted when necessary.

- Meeting venues are selected to minimise travel time for delegates.

- LOC meetings are attended only by HCP/OHS from that country and are held in the country where the LOC is based. If the GSK meeting is held during a third party international meeting (e.g. medical/scientific congress), but outside the specific times of the meeting programme, it must be approved in writing by the Regional Medical Head.

- We may organise international meetings for attendees from different countries, where the logistics, efficiencies and economies of scale can be demonstrated to justify an international meeting.

    - Where an international meeting is organised by LOCs, this is approved by the relevant Regional Medical Affairs Leader. International meetings organised by above country business units are approved by the Category Medical Affairs Director or Regional Medical Affairs Lead (or equivalent) depending on who is accountable for the event.

- Payments may not be made to individual HCP/OHS or groups of HCPs/OHS, either directly or indirectly, to rent meeting rooms.

ⓘ Reference **STD_404715:** *GSK Standard on Meetings and Catering*.

ⓘ In Europe the use of hotels of more than a 4 star rating is not permitted.

6.3. Hospitality

- GSK may only provide or pay for meals for HCP/OHS as part of a scientific, educational, promotional, detailing or business meeting as permitted under the CH Code. Where hospitality is appropriate, it must be incidental and secondary to the meeting itself.
- Any meals (food and beverages) provided incidentally to HCP/OHS do not exceed the local monetary and frequency thresholds (must be defined and documented together with other Business Units operating in same country).
- "Lunch & Learn" or "In Service" events may be organised by commercial sales force in a doctor's office or pharmacy when an HCP/OHS agrees to participate in a learning event during the regular meal break. The meal in conjunction with a "Lunch and Learn" or "In Service" can be provided only in HCP's office.
- Modest meals (such as coffee and snacks) for HCPs/OHS at congresses and symposia are permitted. Such hospitality must not be extended to lunches and dinners.
- We do not organise or fund meetings (see **Section 6.4:** *Funding of third party scientific/medical congresses and other third party meetings*) for HCPs/OHS that are of a social or sporting nature.
- No entertainment or other leisure or social activities are paid for or organised by us at any time (including guided tours, concerts, visiting exhibitions, museums etc.) including in connection with our funded or stand-alone meetings. This includes activities for individual HCPs/OHS.
- We do not invite guests or spouses of those we invite and we do not provide or pay for any hospitality or make arrangements for guests or spouses to attend.

6.4. Funding of third party scientific/medical congresses and other third party meetings

See **Appendix 1:** *Consumer Healthcare Scientific Engagement* for more information regarding independent medical education.

- We only provide financial support for medical/scientific congresses (or other third party meetings) when:
    - The scientific content is reputable and aligned to our scientific or medical interests.
    - The venue meets our requirements (see **Section 11:** *Scientific Engagement*) and has appropriate facilities which are clearly separated from any entertainment, sports, tourist or leisure facilities that may be present.
- Congress funding and activities are reviewed by the LOC in the country in which the congress takes place to ensure compliance with local laws, regulations and applicable industry codes.
- In circumstances where GSK receives an unsolicited request from a medical, scientific or other third party conference organiser for a grant or donation, that funding must follow the Grants and Donations Policy (**POL-GSK-016**) and SOP (**SOP-GSK-016**). In these circumstances, provided GSK does not influence the content of the event or selection of the speakers, it may accept in return a service, privilege or benefit provided that is incidental and substantially less than the funding being sought. If it is not incidental and not substantially less than the funding being sought by the third party, the rules of this Section 6.4 must be applied. If GSK receives services or benefits which is commensurate to the amount paid, then the activity would be considered a promotional activity or scientific engagement activity depending on the content.
- GSK CH may proactively seek a presence at medical/scientific congresses by making payments (e.g. sponsorship or fee for service) to enable promotional activities (e.g. commercial booth space) or scientific engagement activities (e.g. scientific booth space). These activities must be considered sponsorships and must follow the requirements of this CH Code.
- We do not fund medical congresses to enable promotional activities (e.g. commercial booth space, GSK sponsored satellite symposia) before marketing authorisation for a product is granted.
- Sponsorship or fee for service funding of medical/scientific congresses in these products' disease/condition area prior to marketing authorisation may be provided under Medical Affairs accountability prior to marketing authorisation being granted, as per Scientific Engagement requirements.

- Funding may also be provided in the form of a grant to the medical/scientific congress's organisational committee, and in such cases the Grants and Donations policy (**POL-GSK-016**) and SOP (**SOP-GSK-016**) must be followed.

6.5. Funding HCPs/OHS to attend scientific/medical congresses

- We do not provide direct financial support to HCPs/OHS to attend medical congresses or to travel to attend medical congresses.

- We may only provide indirect financial support for HCPs/OHS to travel and attend medical congresses by providing funds to the congress organiser or other independent third party to whom the HCP/OHS can apply (see **process map**). The selection of HCPs/OHS to receive funding is made independently by the third party.

- Funding the congress organiser or other independent third party must follow section 6.4, the Grants and Donations policy (**POL-GSK-016**) and SOP (**SOP-GSK-016**).

6.5.1. Selection of medical congresses

- We may provide financial support to a medical congress or a conference (via an independent third party as explained in section 6.5.2) that is:
  - In disease areas where we have an authorised products.
  - Scientific, medical and/or educational and meets the requirements of this CH Code in respect to the venue and hospitality offered.
- Medical Affairs approves the selection of congresses as part of business plans.

6.5.2. Selection of independent third parties (including congress organisers)

- The independent third party:
  - Is credible and independent.
  - Meets our **ABAC requirements**.
  - Has infrastructure and resources in place to advertise the available award, review and evaluate applications, communicate decisions, manage the provision of the awards and maintain audit-ready documentation.

- Has processes for management, tracking and disbursement of funds.
- Has independent governance controls.
- Signs a **contract** with GSK which includes agreements:
    - Not to provide cash payments directly to HCPs/OHS or their affiliated organisation e.g. university. Payments are made directly to the conference organiser or travel/accommodation agencies.
    - Not to provide the names of HCPs/OHS to GSK unless required by local laws and/or to meet local disclosure requirements.
    - To ensure recipients are made aware that GSK has provided grant funding for the programme.
    - To allow independent audit by GSK or a third party we employ.
- Where the medical congress organiser does not (or will not) operate a scheme through which we can provide funding for HCPs/OHS to attend or the scheme does not meet the requirements above, another independent third party may be sought and selected (see **process map**).

- The General Manager in the country where the HCP/OHS for whom funding has been made available resides, is accountable for following our controls for engaging third parties (e.g. our ABAC framework). The General Manager is accountable for approving the third party and for approving associated budget and expenses provided to the third party. The Category Medical Affairs Director or Area Medical Affairs Leaders as appropriate are accountable for congresses and third parties managed at an above country level.
- We monitor the third party (parties) chosen to provide funding to ensure compliance with the agreed contracts. Monitoring focuses on appropriate financial management and disbursement to applicants that align with the guidance for HCP/OHS selection we provide (see below), or to the selection criteria created by the independent third party to which we provided funds.
- The monitoring does not identify or reveal the names of HCPs/OHS selected, unless there is reason to suspect mismanagement of our funds.

6.5.3. Selection of HCPs/OHS

- The selection of HCPs/OHS to receive funding is made without influence from us. These decisions are made independently by the third party based on merit and need.
- We may provide non-mandatory guidance to the independent third party on selection criteria for HCPs/OHS such as:
    - HCPs /OHS who can show scientific interest in the conference, or can show benefits to their patients from attending.
    - HCPs /OHS who are participating in the conference as presenters or have other active participation in original research or scientific work that is being presented.
    - HCPs/OHS who can share learning with a larger community after the conference because they teach in colleges or postgraduate units, or are part of a larger network of HCPs/OHS anticipating feedback from the conference.
- HCPs/OHS enquiring about the possibility of financial support are referred to the independent third party (i.e. we do not select HCPs/OHS that are referred). We do not assist HCPs/OHS in making applications.

6.6. Funding HCPs/OHS to attend GSK promotional meetings

We do not pay for or arrange travel or accommodation for HCP/OHS to attend our stand-alone promotional meetings.

- An exception can be obtained only if the rationale for the arrangement of travel or accommodation for each individual HCP/OHS to attend is documented and approved in the country where the HCP/OHS resides. These approvals are required before any contact with HCPs/OHS and/or travel or accommodation arrangements are planned.
    - The General Manager of the LOC in the country of the HCP/OHS and the relevant CET member or designee approve exceptions.
    - Exceptions are not permitted for local in-country meetings where HCPs/OHS are from the same hospital, practice or town/city where travel time or distance is not an issue. Such meetings are typically arranged by sales representatives.
    - Exceptions may be considered for national meetings for HCPs/OHS who would need to travel from across the country where the travel distance, time and cost may be more significant. Such meetings are not to be organised by the sales representatives.

6.7. Gifts

- Gifts are anything of value, given as a mark of friendship or appreciation or to express the hope of future business success and without expectation of consideration or value in return.

- Gifts for the personal benefit of HCPs/OHS are not permitted. Provision of cash or cash equivalents as gifts is prohibited. Except for the items expressly permitted in this CH Code (see section below for appropriate cultural courtesy items, **Section 5.11** on promotional aids and **Section 7.4** on items of medical/educational utility) no gift, benefit in kind, or financial advantage may be offered or given to HCPs/OHS.

6.7.1. Cultural courtesy items

- Cultural courtesy items for HCPs/OHS (i.e. items given to acknowledge significant national cultural or religious holidays) are not permitted, other than by exception in some countries in Asia Pacific, Middle East, and the Africa (AMA) Region where it is considered respectful of local customs and permitted under local laws and regulations and provided it is done in a fully transparent way. Examples of cultural courtesy items include moon cakes during Chinese Moon Festival or gift for Chinese New Year.

- Wherever such an exception applies, it is documented and approved by the local or area RMCB with the rationale for respecting the relevant holiday(s), together with the permitted frequency and cost limits (minimal/modest and proportionate within the country) for the items. The limits for cultural courtesy items in any country are consistent across business units in that country.

7. Other non-promotional activities

7.1. Information about our products for the general public

Non-promotional activities outlined in this section 7 must be managed and owned by Medical Affairs and the content and materials related to these activities must be approved via the CCAT process (ZINC). See **Section 3** for promotion to consumers and **Section 7.2** for disease awareness for patients or the general public.

- Non-promotional information about our products which is made to the public either directly or indirectly:

- Is factual, balanced and consistent with the locally approved product information.
- Does not raise unfounded hopes for successful treatments.
- Is not misleading about the safety of the product.
- Is not intended or designed to encourage the patient to ask their HCP to prescribe a specific GSK prescription product.

ⓘ This includes for example, information provided in response to enquiries from journalists and patient advisory groups, information provided through proactive media activities (e.g. press releases) and reference information on public web-sites (see also **STD-340448:** *Standard for interacting with patient organisations* and **SOP-CGA-100**: *Global product and pipeline media materials approval procedure*.

7.2. Disease awareness for patients or the general public

- Disease or condition awareness information directed to patients/general public may be provided directly or via an HCP/OHS. These awareness campaigns can be in partnership with government agencies, semi-government agencies or non-profit organisations.
- Disease awareness campaigns related to prescription products must be GSK branded only and not product branded.
- Disease or condition awareness campaigns related to non-prescription products or consumer products are perceived promotional and have to be performed according to the CH Code. These activities can be product branded and must be managed by Commercial functions with Medical Affairs oversight.
- Where there is a product in development and we do not have an authorised product for a particular disease/condition, disease awareness activity for patient/the general public is not conducted until after any appropriate product authorisation.
- Disease/condition awareness material includes an acknowledgement of GSK involvement and/or funding where applicable.

ⓘ Disease/condition awareness includes information about the characteristics of disease or condition, methods of prevention, screening and available treatments.

ⓘ Disease/condition awareness information may be provided through digital channels subject to this section and **POL-132175:** *Policy for Use of Digital Channels*.

7.3. Healthcare support services

- Healthcare support services are services provided, directly or indirectly, to healthcare organisations (HCO) and/or patients.
- These services are non-promotional and have the objective of achieving better healthcare outcomes for patients, enhancing patient care or benefitting a healthcare system while maintaining patient care (e.g. funding a nurse to identify high risk patients for assessment and health management, analysis of economic data for budget planning). Where permitted by local laws, regulations and/or applicable industry codes we can provide these services.
- Eligibility of medical practices to receive the service is based upon objective criteria linked to the defined purpose. It is not linked to the prescription or use of our products.
- Clinical decisions, which include the selection of appropriate products or the development of treatment management plans, are the responsibility of the prescriber.
- Patient confidentiality is maintained.
- Measures are established for monitoring and processing any adverse event reports that may be received in the course of any healthcare support service.
- Any proposal to provide healthcare support services is reviewed and approved in advance by Medical Affairs and Legal to ensure compliance with applicable laws and regulations. Accountability can be with Medical Affairs or Commercial.
- The recipient signs a contract with GSK which sets out the details of the service, including activities to be performed by the service provider, the responsibilities of the recipient and the defined duration of the service.
- Involvement of GSK in the provision of healthcare support services is disclosed to HCPs/OHS involved and recipients of the service.
- Healthcare support services are kept separate from promotional activities.
    - Healthcare support services can be company branded – they do not include the brand or name of our products.
    - Materials related to the healthcare support service are non-promotional.

- Sales representatives may introduce, but do not provide, deliver, demonstrate or have other involvement in healthcare support services.

- Information collected in the course of providing a healthcare support service is not used for promotion or to plan promotional activity. This information is not shared with sales representatives.

- The success of the healthcare support service is monitored regularly and measured only by reference to criteria directly related to the improved health outcomes that the service is designed to achieve.

The remuneration of those involved in the provision of the healthcare support service is not linked to sales of our products.

7.3.1. Patient Support Programmes (PSPs)

A GSK Patient Support Programme (PSP) is an organised programme implemented by or on behalf of GSK that involves direct or indirect (via a third party) contact with the patient or carer with the aim of either:

- Helping to manage a patient's medication and/or disease outcomes (e.g. adherence, awareness, education), or

- Providing or arranging financial assistance for patients who cannot afford their medication (e.g. reimbursement support, product discount), or

- Providing healthcare professionals with support for their patients.

- The intention of these programmes is to support patient care.

- Generally PSPs are associated with prescription products. When these PSPs are conducted with non-prescription products or consumer products, they would be considered promotional in nature and must follow the CH Code requirements around the specific promotional activities.

- Compliance (or adherence) programmes for patients who use our prescription products are only administered following initial involvement and endorsement of an HCP involved in the treatment of relevant patients.

- Access to Medicines Programmes for our authorised prescription products (i.e. those to support affordability) is reviewed by Medical Affairs and Legal. They are not an improper inducement for HCPs/OHS to prescribe our medicines, or for the patient to

request our medicines. They do not constitute advertising of medicines to the patient except where expressly permitted by local laws.

7.4. Items of medical/educational utility

- Items of medical/educational utility which enhance patient care, the responsible use of products or are beneficial to the provision of medical services can be provided to HCPs/OHS.
- Such items may be offered or provided free of charge if they are infrequent and of modest value (to be defined and documented locally). These items can be company branded or product branded and can carry product claims if they are related to non-prescription or consumer products. If these items are related to prescription products they can be company branded and not product branded (see exception below for patient support items).
- Items we provide do not subsidise the routine operations of any medical practice and may not be provided on long term basis to an HCP/OHS or practice other than in the context of conducting a clinical study.
- Items of medical/educational utility are not provided for sales representatives or other GSK representatives to gain access to a medical facility.

Refer to **Appendix 3:** *Guidance on Consumer Healthcare Promotional Aids and Items of Medical/Educational Utility (IMUs) for Individual HCPs*.

ⓘ Items of medical/educational utility include so-called 'patient support items' which enable patients to gain instruction and experience using their products while under the supervision of an HCP/OHS. Examples include dental models, anatomical models and charts which are not passed onto patients to keep. These items may bear the name of a product and/or information about products only if such detail is essential for the proper use of the item by patients.

ⓘ Items of medical/educational utility are not provided by R&D staff to clinical investigators where the items are unrelated to the conduct of the study.

8. Co-promotion and third party sales forces

- Subject to applicable competition law and guidance issued for particular types of deal, where a third party is co-promoting or promoting a GSK product (i.e. we own any necessary authorisation), the third party complies with the standards set out in

local laws, regulations and applicable industry codes and this CH Code. Promotional materials and activities carried out, by the third party are approved by GSK in accordance with relevant approval processes.

- Where we co-promote or promote a third party's product (i.e. where the Third Party is responsible for any applicable marketing authorisation) we comply with local laws, regulations and applicable industry codes and this CH Code. We seek agreement from the third party to comply with the standards set out in this CH Code.

- Where we utilise the services of a third party sales force to conduct our promotional activities or detailing to HCPs/OHS, we ensure the third party sales force complies with the standards set out in local laws, regulations and applicable industry codes and this CH Code. Promotional materials and activities carried out, by the third party are approved by GSK, in accordance with relevant approval processes. The third party sales force must be provided with the required training on our policies/standards and our products.

9. Collaboration with GSK Pharmaceuticals (RxCx Collaboration)

In markets where Rx Cx collaboration initiatives for promotional activities are implemented, the Rx Cx collaboration plan (or STP) must be approved by the CH Regional Head. If the collaboration covers CH business promoting GSK Pharma owned products, the activities must be conducted in adherence with the GSK Pharmaceutical code **STD_344428:** *GSK Code of Practice for Promotion and Scientific Engagement prescription medicines*.

We can pay HCPs/OHS to speak about our non-prescription products and consumer products. Where commercial staff plans to engage the same HCP/OHS to speak on behalf of CH non-prescription products, uses or promote non-prescription products where Pharma has a prescription product in the same therapeutic area, the activity has to be coordinated with GSK Pharma Medical staff prior the activity commencing and the engagement must be logged for the country CAP reporting.

10. Endorsements

GSK CH can seek endorsement of products, brands, promotional material or detailing aids from professional organisations, such as the country Dermatological Society. Such endorsements must be based on the following criteria:

- Must be obtained from a reputable and recognised organisation which will not bring discredit to GSK or our brands.

- Must be based on formal process, including their review and approval, that the organisation has in place to provide their seal of endorsement.

- Must be based on the organisations independent review of material submitted to them.

- If payment is made for such endorsements, it must be at fair market value based on what the organisation would charge to review the science (research, studies, trial data, etc.) behind the product or promotional material as well as any administrative charges (record of endorsement, website maintenance, etc.).

- The engagement with these organisations, which are typically a healthcare organisation (HCO), to seek endorsement must follow the HCP / HCO engagement process.

- GSK must be transparent about our payment to the organisation. The payment to the organisation must be disclosed as part of the GSK transparency programmes such as EFPIA.

- GSK must not require or request any agreement for exclusivity of endorsement which may limit the organisation endorsing other companies and brands that meet their criteria.

11. Scientific Engagement

Scientific Engagement is the non-promotional interaction and exchange of information between GSK and external communities in order to advance scientific and medical understanding. This includes the appropriate development and use of our products, understanding the management of disease/condition, and improving patient care.

The activities and materials associated with scientific engagement are non-promotional in nature and intent, and proportional to the scientific need. There is a clear distinction between scientific engagement and legitimate promotional activities performed by Commercial Staff. Scientific Engagement activities are to be performed only by Medical Affairs or R&D staff and the activity must be entirely owned by them. See **Appendix 1** for full details on Scientific Engagement.

When CH engages HCPs/OHS for Scientific Engagement the same principles and rules covering fair market value fee structure, approval and governance processes, hospitality,

travel, cap, etc. must be followed as outlined in **Section 6:** *General Requirements for Interactions and Engaging with HCPs/OHS* of this CH Code.

Glossary & Administration

Glossary

ABAC: Anti-Bribery and Corruption

CCAT: Claims and Copy Approval Team (formerly known as Copy Review Committee-CRC)

CME: Continuing Medical Education

CPD: Continuing Professional Development

CTD: Common Technical Document

Donation: The term 'donation' refers to a non-monetary award, such as products, services, equipment, subsidies, employee's time or other assets.

FMV: Fair Market Value

GDS: Global Data Sheet

Grant: A grant is a financial award.

Healthcare Organisation (HCO): The term 'healthcare organisation' means any private or public sector organisation, institution or association that is comprised of HCPs and /or that provides healthcare services, and also includes a clinic or medical practice consisting of one or more HCPs.

Healthcare Professional (HCP): The term 'healthcare professional' or 'HCP' refers to an individual who in the course of their professional activities is authorised to prescribe, purchase, supply, administer or dispense medicines or medical devices.

LOC: Local Operating Companies

Local Regulatory Clearance: all applicable regulatory approvals, clearances, registrations or similar requirements as well as all internal procedures required to be completed prior to the marketing or sale of a product.

Lunch and Learn or In Service: A detailing or promotional session organised by commercial sales force in a doctor's office or pharmacy when an HCP agrees to

participate in a learning event during the regular meal break. This is typically organised to accommodate the busy schedule of the HCP.

Medical Education: Medical Education comprises programmes or activities which have the intent to provide education to HCPs which is across the range of scientific information and therapeutic/prophylactic options relevant to a disease state, balanced, comprehensive and up-to-date, and which may or may not result in the award of Continuing Medical Education (CME) points to participants. These activities are intended to improve and enhance the HCP's skill to engage their patients and deliver care.

Medical information: Scientific and clinical information related to usage, efficacy and safety of any GSK CH product whether on label or off label. It is delivered in response to unsolicited enquiries from HCPs/OHS, including payers and managed healthcare organizations, and consumers.

Medical Society: A medical society is a body of HCPs that specialise in a particular aspect of medicinal practice and who meet to discuss data/ policies/ guidelines and other matters of mutual interest to advance patient care within that discipline.

Non-prescription products: products that are non-prescription by regulatory status and do not require a prescription for dispensing; typically either Over-the-Counter (OTC), Behind-the-Counter (BTC), and general sale

Other Healthcare Staff (OHS): The term 'other healthcare staff' means any person who, in the course of their employment may recommend, purchase, supply or use, or influence the purchase, supply or use, of medicines. Other healthcare staff includes but is not limited to pharmacy assistants, hospital management, primary care managers, members of formulary committees, and payer bodies such as staff in health appraisal agencies, reimbursement bodies, pricing bodies and sick funds.

On Label means that promotional material must be consistent with the approved conditions of use as per the Claims Support Summary or SPC (e.g. local product label).

PIF: Product Information File includes the product description, the safety report, details of methods of manufacture and proof of the effect claimed.

Prescription products: medicines and devices that are prescription only by regulatory status and require a prescription for dispensing

Promotion: The term 'promotion' refers to any activity undertaken by GSK or on its behalf that advertises or promotes the prescription, supply, sale, distribution or use of GSK products.

- **Promotional activity/ material** is any activity/ branded material that advertises or promotes the prescription, supply, sale, distribution or use of GSK products. This includes but not limited to television advertisements, digital material, promotional aids (brand reminders), and point of sale material

RMCB: Risk Management and Compliance Board

SPC: Summary of Product Characteristics is a legal document approved as part of the marketing authorisation of each medicine and is the basis of information for HCPs/OHS on how to use the medicine.

Sponsored satellite symposia are symposia which we fund and organise within the infrastructure of, and officially recognised by, a medical congress.

Stand-alone promotional meetings are meetings we initiate, intended for HCPs/OHS, hosted independently of a congress or other third party meeting, which relate to GSK products and uses, and/or related disease or therapy areas, and are not covered by Scientific Engagement.

Transfer of Value: Any transfer of value, whether of money, in kind or otherwise, made directly or indirectly to or for the benefit of a recipient.

- **Direct transfers of value** are those made directly by GSK to or for the benefit of a recipient.

- **Indirect transfers of value** are those made on behalf of GSK to or for the benefit of a recipient, or transfers of value made through an intermediate and where GSK knows or can identify the recipient.

Administration

Endorsement:	Sean Roberts, Chris Kocun, Brian McNamara, Zubair Ahmed, Richard Slater, Carlton Lawson
Owner:	Sean Roberts, SVP Legal Operations and Compliance Chris Kocun, Chief Medical Officer Consumer Healthcare
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STD-CHC-01, GSK Code of Practice for Promotion and Customer Interactions v1

Waivers and Exceptions

Any requirement of this CH Code as it relates to promotional practices may be waived conditionally on a case-by-case basis in very exceptional circumstances with written indication from the Consumer Healthcare Compliance Officer as approved by the CH Code sponsor. All requests for exceptions/exemptions must be directed to Global Ethics & Compliance (GEC).

Any exceptions of this CH Code as it relates to Scientific Engagement must be approved by Consumer Healthcare Chief Medical Officer.

Once approved, these exceptions will be recorded by GEC. The approved exception author/sponsor is required to notify all relevant GSK employees, contractors and third parties of the granted exception.

Related Documents

1. GSK written standards for activities and interactions with audience groups not covered by this CH Code

Activity/Audience Group	GSK written standard
Approving promotional materials	- SP1910: Claim & Copy Approval - WI1484: Claim & Copy Approval
Clinical research	- POL-GSKF-408: Human subject research.

Engaging healthcare professionals and other health care staff to provide a service	- SOP_344448: Engaging with Healthcare Professionals (HCPs) to provide services - SOP-GSKF-417: Disclosure of transfers of value to HCPs and HCOs domiciled in Europe/Russia/Ukraine/Turkey. - Consumer Healthcare Guidance on Engaging HCPs - Medical Governance in Consumer Healthcare for Engagements with External Experts.
Humanitarian product donations	- POL-GSK-303: Humanitarian product donations policy. - SOP-GSK-303: Humanitarian product donations standard operating procedure and emergency response.
Interacting with government officials	- SOP-GSK-007: Interactions with officials from government and inter-governmental agencies.
Interacting with the media	- POL_87160 POL-GSK-301: External and internal communications activities on behalf of GSK. - SOP_191843 SOP-GSK-301: External and internal communications activities on behalf of GSK. - SOP-CGA-100: Global product and pipeline media materials approval procedure
Interacting with patient groups	- STD-GSK-PAG: Standard for interacting with patient organisations.
Market research	- SOP-CHC-451: Consumer Healthcare Global Insights and Market Research SOP
Medical information	- SOP-CHC-409: Consumer Healthcare Medical Governance - WI1435: Management of Medical Information Enquiries
Procurement for meetings	- STD-GSK-512: Travel, meetings and expense standard for GSK employees. - STD_404715: GSK Standard on Meetings and Catering
Providing grants and donations	- POL-GSK-016: Policy on grants and donations.[to be updated] - SOP-GSK-016: Grants and donations SOP.[to be updated]
Using digital channels for external engagement	- POL-132175: Policy for use of digital channels

2. Key written standards for external interactions

Topic area	Written standard
ABAC Framework for engaging third parties	- ABAC - STD_455141: Anti-Bribery and Corruption Standard
Engagement of third parties	- POL-GSK-007: Policy on preventing corrupt practices and maintaining standards of documentation. - Anti-bribery and corruption framework. Third party procedures and guidance.
Disclosure of transfers of value	- SOP-GSKF-417: Disclosure of transfers of value to HCPs and HCOs domiciled in Europe/Russia/Ukraine/Turkey - POL-TDOR-001: Transparency data operations and reporting (TDOR) policy
Maintaining privacy and confidentiality	- POL-GSK-010: Privacy of personally identifiable information.
Safety reporting	- POL-GSK-400: Management of human safety information for GSK products.
Sanctions and Export Control	- POL-GSK-014: Policy on Sanctions and Export Control - SOP-GSK-014: Procedure on Sanctions & Export Control.

Appendices

Appendix 1: Consumer Healthcare Scientific Engagement

Scientific Engagement

Appendix 2: Template for CH Code Local Adaptations

Template for CH Code Local Adaptatio

Appendix 3: Consumer Healthcare Promotional aids and Items of Medical/Educational Utility (IMUs) for individual HCPs

CH Code -
Promotional Aids and