

Ethical conduct

We are committed to creating a strong ethical culture at GSK. We do this by putting the appropriate policies in place, recruiting the right people and equipping them with the tools to make ethical decisions.

Headlines

- Carried out a wide-ranging review of our corporate ethics strategy
- Added questions on ethics and integrity to our recruitment process and GSK Managers Interview Guide
- Began extending our independently managed integrity helpline to all countries where we operate
- Over 14,000 managers completed our self certification process in 2007
- 11,000 sales and marketing staff in our Pharmaceuticals International region received training on our revised International Promotion and Marketing Code
- 1,535 employees were disciplined for policy violations, of which 320 were dismissed or agreed to leave the company voluntarily
- Issued an apology in Australia and New Zealand for inadvertently misleading *Ribena* advertisements

Strong policies, codes of practice and good training are essential elements of our approach. However, on their own they cannot guarantee that our employees will meet our standards. Our internal compliance systems are designed to identify and address breaches of our codes.

There is a strong business case for achieving high standards of ethical conduct:

- Greater stakeholder trust in GSK and our products including among regulators, doctors and patients
- Improved risk management by preventing breaches of our ethics policies which could have serious financial or legal consequences
- Competitive advantage due to better reputation and reduced costs of failures

We completed a thorough review of our compliance and risk management strategy in 2007 and are improving our programmes in a number of areas as a result.

Putting the patient first is at the heart of ethical conduct for a pharmaceutical company. This means maintaining high ethical standards during all stages of R&D (see [research practices](#) page 55) and once a product is approved for marketing.

Marketing ethics is a particularly important aspect of ethical conduct for GSK and one that is relevant to patient safety. It is essential that our marketing practices help doctors to prescribe medicines that are in the patient's best interests. Our policies prohibit kickbacks, bribery or other inducements to doctors, and any promotion for unapproved uses of our medicines.

Our approach

Our Code of Conduct

Our Employee Guide to Business Conduct requires all employees to act with integrity, comply with the law, avoid conflicts of interest and report any violations or unethical behaviour. It provides guidance, including specific examples, on what constitutes unacceptable behaviour.

Read our [Code of Conduct](#), [Employee Guide to Business Conduct](#), and [management certification statement](#) in the background section of our website.

Marketing ethics

We market our medicines to doctors, hospitals and governments. In some countries, such as the US, we also advertise medicines directly to consumers. Our specialist sales representatives meet regularly with doctors and pharmacists to inform them about our medicines and their approved uses.

We believe that sales representatives play an important role in providing up-to-date information to doctors on our products and their benefits to patients. However, we recognise that the marketing of pharmaceutical products raises some challenging issues.

In particular, some people are concerned that marketing by pharmaceutical companies exerts undue influence on doctors, that sales representatives do not always give doctors full information about potential side effects, or that promotion for unapproved uses may be occurring despite increased training, monitoring and oversight. Our approach to addressing these issues includes regional marketing codes of practice, regular training and monitoring.

Marketing Codes of Practice

Our Pharmaceutical Marketing and Promotional Activity policy applies to all employees and agents. It commits us to promotional practices that are ethical, responsible, principled and patient-centred. It prohibits kickbacks, bribery or other inducements to doctors, and any promotion for unapproved uses of our medicines.

This policy is supported by regional marketing practices codes in Europe, our Pharmaceuticals International region, Japan and the US. These codes apply the same standards but reflect differences in market structures, national healthcare systems and regulations.

A copy of the [GSK European Promotion of Medicines Code of Practice](#) is available in the background section of our website.

Our Marketing Codes of Practice in summary

- **Full and accurate information – information can only be provided on approved uses for a medicine. It must be based on valid scientific evidence, and must be accurate, balanced, fair, objective, unambiguous and up-to-date**
- **Promotional items to healthcare professionals – branded promotional items must be given only occasionally and must be relevant to the practice of medicine. Their nominal value must be no more than \$10 or less than £6 in the UK. Items cannot be given as an inducement to prescribe any of our medicines or to medical professionals retained as consultants to GSK**
- **Appropriate hospitality for meetings – no entertainment is permitted. Hospitality (such as travel costs or food) may only be provided for meetings with an educational purpose. The level of hospitality must be appropriate to the occasion and must only be provided for relevant healthcare professionals, not spouses, children, office personnel or any other guests**
- **Decisions about grants for medical education are reviewed by qualified medical or scientific personnel or, in the US, within our compliance function**

Our relationship with healthcare professionals

As well as our marketing codes we have detailed policies and monitoring systems governing our relationship with healthcare professionals. For example, we have established the following controls and processes in the US:

- Limits on payments to healthcare professionals through speaker and consultancy fees
- GSK funding of grants to patient groups cannot exceed 25 per cent of the group's annual income
- A new Speaker Evaluation Process implemented in 2007 covering healthcare professionals sponsored by GSK. This requires our regional medical scientists to evaluate high frequency speakers, and to provide feedback on their effectiveness and compliance with the GSK Speaker Programmes policy

It is in our interest that the physicians we work with do not receive excessive funding from GSK. This could undermine their objectivity and lessen the time they spend with patients or conducting research, potentially reducing their professional credibility and their value to GSK as sources of current medical expertise.

All GSK employees dealing with healthcare professionals undergo extensive training and monitoring.

Training and awareness

Training and awareness programmes help employees understand the importance of ethical conduct and to apply our policies in practice.

New employees in the UK and the US complete induction training on our Code of Conduct. Our annual management certification programme requires managers to confirm that they comply with our ethics policies. The programme covers over 14,000 managers worldwide. Read our [management certification statement](#) in the background section of our website.

Managers can access three e-Learning modules on ethical leadership.

Specialised training is provided for employees working in R&D, manufacturing and sales and marketing where there are additional regulatory requirements.

Training for employees working in sales and marketing includes:

- Induction training and testing on our marketing code of practice
- Detailed training for sales representatives on the medicines they promote and the diseases they are designed to treat
- Regular refresher courses held at least once a year
- Regular management updates in Europe and the US on the types of unethical conduct detected and disciplinary actions taken

Supporting industry codes of conduct

GSK supports efforts to strengthen marketing standards across the pharmaceutical industry. This benefits us by creating 'a level playing field' in the countries in which we operate and helps to improve the reputation of the pharmaceutical industry as a whole.

For example, in 2007 the Australian Competition & Consumer Commission (ACCC) introduced a new requirement for members of Medicines Australia (MA), an industry association, to fully disclose details of all educational meetings and symposia, including details of hospitality provided.

We fully supported the ACCC's position. We believe that by demonstrating compliance with the MA Code of Conduct we can improve public confidence in our industry and show that our relationships with patient groups and healthcare professionals are conducted according to high standards.

Monitoring and compliance

Our corporate ethics and compliance department promotes effective compliance programmes, addresses compliance issues, and reports problems and progress to senior management and the Board.

We have a dedicated compliance officer in each of our eight business units – R&D, Manufacturing, Biologicals, Pharma Europe, Pharmaceuticals International, Consumer Healthcare, Japan Pharma and US Pharmaceuticals, and additional compliance representatives in some markets.

Compliance officers are senior managers with direct access to the leadership teams of GSK functions. They are a source of expertise for anyone with a question on ethics or GSK policies. Our corporate compliance officer reports directly to the CEO.

Monitoring for sales and marketing

Sales representatives are supervised by their managers who regularly monitor educational events, visits to doctors and expenses. We use a risk-based approach to determine the frequency of our checks on different districts and individual sales representatives.

In the US we monitor the requests for Medical Information letters on off-label topics by sales representatives to check that representatives are not promoting off-label uses for our products. Our internal audit department regularly audits our sales and marketing practices globally.

Reporting channels

Employees are encouraged to seek help and to report any concerns or suspected cases of misconduct. They can do this through their line manager, a compliance officer, or through our confidential Integrity Helplines or offsite post office box (in the US).

Reporting channels are promoted through the Employee Guide to Business Conduct, on the GSK intranet and during training.

Addressing misconduct

Our Corporate Ethics and Compliance department monitors and tracks allegations and suspected legal, ethical or policy infractions. It ensures that all such allegations are appropriately investigated. Disciplinary action, up to and including dismissal, is taken where necessary.

Direct-to-consumer advertising

In the US we advertise our prescription medicines to consumers through TV and print advertisements. This is known as direct-to-consumer (DTC) advertising. New Zealand, Bangladesh and Korea also allow limited DTC advertising. DTC advertising of prescription medicines is not permitted in other markets.

Promoting the use of prescription medicines directly to consumers can raise concerns. Critics believe that it encourages people to request unnecessary treatment, adding to the burden on healthcare systems.

We believe that responsible pharmaceutical advertising is a useful source of health information for patients. It helps to increase knowledge of conditions and educates patients about treatment options. In countries such as the US where

DTC advertising is common industry practice, we would be at a competitive disadvantage if we did not promote our products in this way.

Patients must still consult with their physicians about their condition, the appropriateness of a prescription medicine, and obtain his or her consent before receiving such medicines.

Prescription medicines in the US

Our DTC Communications policy is based on the PhRMA Guiding Principles on DTC advertising for prescription medicines.

We have a detailed approval process for DTC advertising, which includes review by legal, regulatory and medical specialists as appropriate. All US marketing employees have received training on our DTC policy.

All DTC television advertisements (including audio and visual components) are submitted to the US Food and Drug Administration (FDA) for review at least 30 days in advance of broadcast.

Members of the public and healthcare professionals can send comments or complaints on DTC advertising to PhRMA's Office of Accountability, which reports the comments and the responses of the companies to the FDA.

The FDA Amendments Act 2007 imposes new restrictions on DTC advertising. It gives the FDA the ability to require submission of DTC television advertisements 45 days prior to dissemination and imposes a new standard on presentation of safety information in broadcast advertisements. Companies responsible for false or misleading DTC advertisements can now be fined up to \$500,000. We are implementing these provisions in our DTC advertising in line with the Act's requirements.

We fund disease awareness campaigns which are designed to increase understanding of a specific disease but are not linked to the promotion of GSK products. These are also governed by our DTC policy.

Our principles for DTC advertising in the US

Our policy states that DTC advertising should:

- Only begin after we have spent an appropriate amount of time educating doctors and healthcare professionals about new medicines
- Be designed to educate consumers about the medicine and the condition for which it is prescribed
- Be accurate and supported by evidence
- Include information on the risks and benefits of treatments
- Provide information on other treatment options (such as diet and lifestyle changes), where these are referenced in the prescribing information for a product
- Only be targeted at an audience at least 80 per cent of whom are adults

Over-the-counter medicines and consumer healthcare products

Our advertising for over-the-counter medicines, oral healthcare and nutritional products is governed by national regulations or codes of practice for advertising. Our over-the-counter medicines are also promoted to pharmacists, doctors and dentists by our sales teams.

We belong to the Consumer Healthcare Products Association in the US and comply with its [Code of Advertising Practices for Non-prescription Medicines](#).

GSK Consumer Healthcare advertising is reviewed by Copy Review Committees (in our larger markets) or medical and legal personnel (in our smaller markets) before publication to ensure it meets our standards.

Advertising to children

Our guidelines for advertising to children prohibit advertising designed to appeal to, or targeted at, children below the legally mandated minimum age. For example, to comply with our guidelines in the UK we do not buy advertising space in children's media and we do not supply vending machines to primary schools.

Sports star sponsorship is important to brands such as *Lucozade Sport*. Our guidelines state that only people who set an appropriate example should be used for sponsorship, and they should have an appeal that is not solely to children below the age of 13.

Our performance

Reviewing our compliance and risk management strategy

During 2007 we carried out a wide-ranging review of our corporate ethics strategy. This included conducting interviews with peer companies, comparing our performance against annual benchmark statistics from the Compliance and Ethics Leadership Council, an industry organisation, and individual discussions on our ethics strategy with GSK senior management.

We found that our internal control framework is fit for its intended purpose and complies with the requirements of the UK's Combined Code on Corporate Governance. We also found our compliance programme to be consistent with the US Federal Sentencing Guidelines and the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers. We identified a number of areas for improvement. Following the review, our focus will be on further embedding an ethical culture at GSK and ensuring we give employees the tools to make the right decisions.

We are focusing on the following areas:

- Recruitment – we have included questions on ethics and integrity in the recruitment process and GSK Managers Interview Guide and will be carrying out more extensive pre-employment checks. This will help ensure we recruit people who share GSK's values
- Management objectives – we will be establishing ethical leadership objectives for the top 1,800 GSK managers. In the longer-term we are looking at ways we can further recognise and reward strong ethical behaviour
- Training – when delivering employee training we plan to include an ethics component and further improve our existing ethics training programmes. We plan to extend ethics and compliance induction training to new employees worldwide. Extra training and guidance will be provided for employees committing minor breaches to prevent them committing serious breaches in future
- Integrity helpline – we will extend our independently managed helpline to all countries where we operate. Employees will be able to call in their native language. An extensive communications campaign will be undertaken in conjunction to raise awareness of the international helpline
- Senior management – we are developing new training and awareness programmes for site directors and general managers who are key representatives of GSK in the countries and locations where they work. This will include individual briefings by the executive team for new appointees on their compliance responsibilities

Progress on meeting our strategy review objectives will be reviewed twice a year by the GSK Board Audit Committee.

Relationships with healthcare professionals

We updated our policies in the US regarding relationships with healthcare professionals. This included launching a new Speaker Evaluation Process to review the effectiveness of frequent speakers and assess their compliance with our speaker policies.

We implemented a new State Reporting System to improve our reporting of expenditure with healthcare professionals, in line with legislation in several US states. The system will allow us to identify and investigate situations where excessive meals and gifts may have been provided by GSK.

In GSK Japan, payments to individual healthcare professionals and medical institutions are also monitored on a quarterly basis to check for any excessive and inappropriate payments.

Questions from doctors on off-label uses for our products must be referred to our medical information department except in very specific instances relating to some oncology and HIV products. In the US, we improved our process for monitoring these referrals to help us ensure that representatives are not promoting off-label uses. We now monitor both the volume of letters responding to questions and the types of referrals made by our individual representatives, for example the number of referrals relating to a particular product or a particular off-label use.

Training and awareness

Over 14,000 managers completed our self certification process in 2007. Other training and awareness initiatives vary from region to region and included:

- 11,000 sales and marketing staff in our international region received training on our revised Pharmaceuticals International Promotion and Marketing Code
- 831 US field sales managers and 228 marketing staff (the employees responsible for overseeing sales representatives) attended our new Compliance University programme at venues across the US. The programme provided a half day interactive course on key compliance areas. Senior managers and compliance officers also attended to answer questions from attendees, help them to explore potential ethical dilemmas and reinforce the importance of the subjects covered
- Country compliance officers and contacts in Europe received training on topics such as key corporate policies, ethical dilemmas, and records management
- Targeted communication and training for R&D employees who engage with external experts (including healthcare professionals). This included e-learning modules covering use of external experts and payments to healthcare professionals and the provision of gifts
- Launched a coaching excellence programme in GSK Biologicals to help new employees understand and adopt GSK values and develop their skills
- Annual online promotion compliance training for all GSK Japan employees who meet with healthcare professionals

Every two years we conduct a leadership survey of GSK managers. The last survey in 2006 showed that 91 per cent of GSK managers believe 'people in my department show commitment to performance with integrity.' 76 per cent agreed with the statement that 'I can report unethical practices without fear of reprisal', considerably higher than the overall industry benchmark of 68 per cent.

Ethics training in practice

Ethics training helps employees make the right decisions and apply our policies in practice. For example, new employees are encouraged to ask themselves the following questions before making a decision:

- Would I be embarrassed if my friends or family knew what decision I have made?
- How would my decision look to a cynic?
- What could the newspaper headline look like?
- Am I still confident that this is the right decision for GSK?

We also run ethical decision-making training for established employees and leaders. During training employees explore ethical dilemmas they may face in their work and receive guidance to help them understand the appropriate response. This is one example of an ethical dilemma:

Your team has received approval to hire a vendor to help with a business task for which there is no internal GSK support. You have asked for and received proposals from three vendors during the specified 'request for proposals' period. After the initial proposal period is over you find out that a good friend is the sales representative for a business who can handle the job for a competitive price.

- Which sections of GSK's policies will help you to make a decision on how to act in this situation?
- Which option is the correct approach:
 - a. Call your friend and ask him to submit a proposal even though the RFP period is over
 - b. Speak with your manager or your compliance officer before making a decision
 - c. Move forward with the proposals you have collected and make a mental note to ask your manager if you can include your friend in the RFP for the next project

The best solution is to move forward with the proposals you have already collected, answer c.

Monitoring and compliance

We established a new fraud risk assessment tool to help us prevent financial fraud. Our finance leadership team will review all financial fraud cases on an annual basis.

Addressing misconduct

In 2007:

- 1,535 employees were disciplined for policy violations
- Of these, 320 were dismissed or agreed to leave the company voluntarily (known as separations)
- Other disciplinary actions included documented warnings (1,215 instances) and financial penalties
- The 1,535 disciplinary actions included 476 cases of employees breaching sales and marketing codes
- These 476 cases resulted in 59 dismissals or separations from the company. All the other 417 cases resulted in documented warnings

In addition to appropriate discipline, employees staying with the company received retraining and increased monitoring. In some cases retraining is also extended to an employee's colleagues to prevent them making similar mistakes.

The main types of violations this year included:

- Marketing and promotional activities
- Good manufacturing /good distribution practices
- Falsification of documents
- Travel and expenses claims

Direct-to-consumer advertising

We developed a new online direct-to-consumer (DTC) training module and certification programme for new marketing employees in the US.

No problems with GSK US DTC advertising were identified by the FDA.

Responsible marketing for our weight-loss treatment

Nearly one-third of US adults are clinically obese and another third are seriously overweight. This is causing a dramatic increase in life-threatening medical conditions such as heart disease and diabetes, and adding strain to the healthcare system. But even a small amount of weight loss can greatly reduce the risk of developing associated medical problems.

In 2007, GSK launched *alli* (orlistat 60 mg), the first over-the-counter weight-loss product to be approved by the US Food and Drug Administration. It helps overweight adults lose weight by preventing about 25 per cent of dietary fat from being absorbed in the gut. Because the treatment can be bought without a prescription it is vital that *alli* is marketed responsibly so it is used in the right way and only by those who need it.

Before launching the treatment we distributed over 65,000 education packs to physicians, dieticians and pharmacists to ensure *alli* is sold appropriately and patients receive the right information about the treatment. Our marketing emphasises that *alli* is not a magic weight-loss pill and requires lifestyle changes to produce the right results:

'You can't just try alli, you have to commit to it. You have to challenge yourself, work hard, and change what you eat.'

GSK chose the name *alli* (pronounced al-eye as in alliance) to emphasise that the drug must be partnered with exercise and a low-fat diet. *alli* comes with educational materials and tools to help users plan their meals and develop an exercise programme. A special website, www.myalli.com, provides further support, allowing people to set targets and track their weight loss. It includes an 'am I ready for *alli*?' quiz which asks potential users to confirm their commitment to moderating their diet, taking exercise and reading the label carefully. All marketing and support materials emphasise that taking *alli* without switching to a low-fat diet may cause side effects related to how the product works.

alli was launched in June 2007 and there were five million visits to www.myalli.com in the first three months after product launch, with the average visitor spending over eight minutes learning about the brand. Over two million starter packs were purchased by October, helping overweight adults learn how to eat healthier foods and use *alli* to lose 50 per cent more weight than through dieting alone.

We received comments from the PhRMA Office of Accountability relating to GSK DTC print advertisements for six products: *Advair*, *Boniva*, *Avodart*, *Requip*, *Lamictal* and *Vesicare*. In each case GSK provided to the Office of Accountability, and the individual that raised the comment, a strong justification that its advertisement complied with the PhRMA Guiding Principles. No changes were made to the advertisements as a result of the comments received.

Targets and key performance indicators (KPIs)

We have set ourselves the following objectives for 2008 and 2009:

- Refresh and update our ethics induction training for new employees worldwide
- Set ethical leadership objectives for our top managers
- Extend our integrity helpline to cover all countries where we operate using many native languages
- Streamline and improve the administration of our corporate policies and procedures
- Embed ethics and integrity concepts in all applicable business training

The future

Our focus over the coming year and beyond will be implementing the findings from our compliance and risk management strategy review. We will be focusing in particular on the following challenges:

- The need to further embed high ethical standards into the GSK culture
- Ensuring a consistent and comprehensive approach is taken across all GSK functions and the different countries in which we operate
- Ensuring our approach continues to meet best practice and reflects changes in the law and stakeholder expectations
- Working to recruit and train high-performing, ethical employees

Apology issued for *Ribena* advertising

It is important that all our advertising and marketing meets the highest ethical standards and is honest and accurate. Unfortunately, sometimes mistakes are made.

GSK issued an apology in Australia and New Zealand after it was found that our advertisements contained information that misled our consumers about the vitamin C content in *Ribena Ready-to-Drink* (RTD) variants in the *Ribena* range of products in those two markets.

Laboratory experiments by two Auckland schoolgirls discovered that *Ribena* RTD did not contain the amounts of vitamin C they anticipated. This led to further testing by regulators in New Zealand and the discovery that the RTD products did not contain the minimum stated levels of vitamin C. Also statements on the cartons that blackcurrants used in the product have 'four times' the vitamin C of oranges implied a high level of vitamin C in the drink. As a consequence GSK was prosecuted in New Zealand and fined NZ\$227,500 (£84,000) for inadvertently misleading consumers.

We investigated our production methods and found a fault in the process designed to test the vitamin C content. We also updated the on-pack information for RTD products to remove all references to vitamin C levels until the problem was remedied. We also stopped using the 'four times' statement.

Following the publicity and court decisions about this misrepresentation, sales of our *Ribena* drinks in New Zealand fell by 12 per cent. We ran an advertising campaign, featuring the heads of GSK Consumer Healthcare in Australia and New Zealand, apologising for inadvertently misleading consumers. We are working hard to regain trust in our brand, and sales are returning to earlier levels.

We have also tested the vitamin C levels in *Ribena* products in all other markets. This testing has confirmed that they contain the stated levels of vitamin C described on product labels.



A lot of GSK employees were dismissed for unethical conduct. Are your policies working?

In 2007, 320 employees were dismissed or agreed to leave the company voluntarily as a result of policy violations. Unethical conduct occurs in all companies. We believe these figures demonstrate the effectiveness of our monitoring and compliance programmes. Furthering our ethical culture, recruiting the right people, providing the right training and tools, improving our checks, and encouraging people to speak-up enable us to identify and address unethical conduct in a consistent and responsive manner.

Is GSK unduly influencing doctors?

We take several approaches to protect against inappropriate influence of doctors including regional marketing codes of practice, regular training and monitoring. Our policies apply to all employees and agents and commit us to promotional practices that are ethical, responsible, principled and patient-centred. They prohibit kickbacks, bribery or other inducements to doctors, and any promotion for unapproved uses of our medicines. Our sales force is regularly trained and supervised by managers who monitor educational events, visits to doctors and expenses.

How do you prevent off-label promotion?

All GSK employees dealing with healthcare professionals undergo extensive training and monitoring. They are instructed that only full and accurate information may be provided on approved uses for a medicine. It must be based on valid scientific evidence, and must be accurate, balanced, fair, objective, unambiguous and up-to-date.

Questions from doctors on off-label uses for our products must be referred to our medical information department except in very specific instances relating to some oncology and HIV products. In the US, we improved our process for monitoring these referrals

to help us ensure that representatives are not promoting off-label uses. We now monitor both the volume of letters responding to questions and the types of referrals made by our individual representatives, for example the number of referrals relating to a particular product or a particular off-label use.

Additionally, our internal audit department regularly audits our sales and marketing practices globally.

Links

In this report:

- [Research practices](#)
- [Supply chain](#)

In the background section of our website:

- [GSK Code of Conduct](#)
- [Employee Guide to Business Conduct](#)
- [Management certification statement](#)
- [Our European Promotion of Medicines Code of Practice](#)

Other resources:

- US Consumer Healthcare Products Association www.chpa-info.org
- UK Advertising Standards Authority www.asa.org.uk
- Information on *alli* www.myalli.com