Distribution and marketing of drugs in the UK (England and Wales): overview

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distribution.pre-conditions-for-distribution

1. What are the legal pre-conditions for a drug to be distributed within the jurisdiction?

Authorisation
To be used or sold in the UK, a drug must have a marketing authorisation that is effective in the UK, either by:

- A centralised application (applied for through the European Medicines Agency (EMA)).
- A national application, which may or may not have been obtained through either of the other EU mechanisms, which are the decentralised and mutual recognition procedures.

A company that holds a manufacturer's licence (regulation 17, Human Medicines Regulations 2012 (HMRs)) can only sell the product to the holder of the marketing authorisation. Any other person wanting to trade in the product in the European Economic Area (EEA) and that is not the marketing authorisation holder or their contract manufacturer must hold a wholesale dealer's licence (regulation 18, HMRs).

Exceptions
There are exceptions for parallel imports of drugs with no therapeutic difference from ones already licensed in the UK and for compassionate use or "specials".

2. Do any types of named patient and/or compassionate use programmes operate? If so, what are the requirements for pre-launch access?

Unlicenced medicines can be supplied to meet the needs of individual patients (regulation 167, Human Medicines Regulations 2012). These are known as "specials" and are only permitted where the drug is:

- Supplied in response to an unsolicited order.
- Manufactured and assembled in accordance with the specification of a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber or for use under the supervision of a pharmacist in a registered pharmacy, a hospital or a health centre and the drug is manufactured under that supervision.
- For use by a patient whose treatment requires the prescriber to be directly responsible for fulfilling the special needs of that patient.

If a "special" is manufactured in the UK or a country outside the European Economic Area (EEA), the manufacturer must hold a manufacturer's (specials) licence issued by the Medicines and Healthcare Products Regulatory Agency (MHRA). If the product is manufactured in the EEA, but not in the UK, the manufacturer must have an authorisation to do so under EU legislation. If a "special" is distributed or imported through a wholesale dealer, that wholesale dealer must hold a licence in relation to that product. A "special" cannot be advertised and records must be kept and serious adverse drug reactions reported to the MHRA.

Separately, the UK has enacted the authorisation requirement under Article 126a Directive 2001/83/EC on the Community code relating to medicinal products for human use, under which the MHRA can grant such an authorisation if:

- No other marketing authorisation for a drug or a registration for a traditional herbal product is either in place or has been applied for and is pending.
- The MHRA considers that placing the product on the market in the UK is justified by public health reasons.
- The product is imported from another member state in which it is authorised.
- The applicant is established in the EU.

Since April 2014, the MHRA has put in place an early-access scheme for products treating, diagnosing or preventing life-threatening, chronic or seriously debilitating conditions with a high unmet need. This scheme provides patients and prescribers with a means for checking the validity of claims that the benefits of a medicine outweigh the risks as a treatment for one of these conditions. It is seen as an interim measure to fill the gap between completion of phase III trials and the issue of a marketing authorisation. The Early Access to Medicines Scheme (EAMS) is voluntary and consists of a two-step evaluation process:

- The promising innovative medicine (PIM) designation.
- The early access to medicines scientific opinion.

The PIM can be applied for during clinical development where this shows that the product is likely to demonstrate significant benefit for patients suffering life-threatening or seriously debilitating conditions. The application can be for a new indication of an already marketed drug. The three conditions to be met are:

- The condition must be life-threatening or seriously debilitating.
- There is a high unmet need (that is, there is no available treatment or existing treatments have serious limitations).
- The potential adverse effects are likely to be outweighed by the benefits (based on preliminary scientific evidence).

Once a PIM has been obtained, an early access to a medicines scientific opinion can be applied for. It is this opinion that is intended to support prescribers when making decisions about treating patients suffering conditions that are life-threatening or seriously debilitating. Following a positive scientific opinion, the MHRA
publishes a public assessment report on the product and their opinion, with details including:

- Summaries of the key clinical studies.
- Risk or benefit analysis.
- Any uncertainties and measures to monitor and manage risk.

Regular updates must be provided to the MHRA and the scientific opinion must be renewed every 12 months, when any clinical or other data generated in the interim is considered.

**Licensing**

3. What is the procedural structure regarding licensing a drug for distribution?

**Structure and regulatory authority**

Drugs must be licensed by a competent authority, which is either the:

- European Medicines Agency (EMA) through a centralised procedure (see below) where this is applicable to the particular products.
- National "competent authority", through a national procedure, for all other products and which in the UK is the Medicines and Healthcare Products Regulatory Agency (MHRA).

These national procedures may or may not be part of EU decentralised or mutual recognition procedures. Applications for a marketing authorisation are provided for in Part 5 of the Human Medicines Regulations 2012 (HMRs). Applications must be made in accordance with Annex I to Directive 2001/83/EC on the Community code relating to medicinal products for human use.

The centralised procedure is compulsory for the following types of drugs:

- Drugs for the treatment of human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS), cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions and viral diseases.
- Medicines derived from biotechnology processes, such as genetic engineering.
- Advanced therapy medicines, such as gene therapy, somatic cell therapy or tissue-engineered medicines.
- Officially designated "orphan medicines" (medicines used for rare human diseases).

The centralised procedure is optional for the following types of drugs (which are otherwise authorised nationally):

- Drugs that are a significant therapeutic, scientific or technical innovation.
- Drugs whose authorisation is in the interest of public health.

Applications through the centralised procedure are submitted to the EMA. The EMA's scientific committees take up to 210 active days plus “clock stops”, at the end of which the committee adopts an opinion on whether the medicine should be marketed or not. This opinion is transmitted to the European Commission, which is then responsible for granting the marketing authorisation.

4. Is there a simplified licence proceeding, or relaxed licensing conditions, for drugs which have already been licensed for distribution in another jurisdiction?

There is a UK Parallel Import Licensing Scheme that allows drugs authorised in other EU member states to be marketed in the UK.

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provided the imported products have no therapeutic difference from the equivalent UK products (regulation 172, Human Medicines Regulations 2012, which refers to the EU parallel import licensing regime). An application is made to the Medicines and Healthcare Products Regulatory Agency (MHRA), which examines the licence given to the product in other jurisdictions and decides whether a parallel import licence should be granted.

There are three levels of "therapeutic similarity" for the purpose of a parallel import licence, each requiring a different complexity of application:

- A “simple” licence, where the products being imported are made by the same group of companies or under licence from the same licensor that holds the UK marketing authorisation.
- A standard licence, where there is no common origin, but the application is not seen as complex.
- A “complex” licence, which is required where there is no common origin and where any of a list of risk factors (being specific differences in manufacturing processes) applies.

For the standard and complex categories, the parallel importer is responsible for the pharmacovigilance for the product.

5. Is virtual drug distribution possible from your jurisdiction?

A wholesale dealer's licence allows its holder to obtain supplies of drugs from the marketing authorisation holder or another EU member state-authorized dealer for that particular activity. Distribution of a medicinal product by way of wholesale dealing, or possession for the purpose of such distribution, must be through distribution activities carried on, or through holding product held, at premises located in the UK as specified in the licence (regulation 18(3), Human Medicines Regulations 2012). Given that distribution activities do not necessarily require that a product be "held" in the UK, as long as the activities relating to distribution are undertaken in the UK, products can be distributed virtually, that is, without ever entering the UK. The Medicines and Healthcare Products Regulatory Agency (MHRA) has indicated that it is used to handling wholesale dealer licences where the physical product is in another European Economic Area (EEA) member state and never actually enters the UK. The wholesale dealer must nevertheless have a named qualified person to supervise and authorise the activities and the MHRA can check the records kept regarding the wholesale dealing activities. Although the products never enter the country, the guidance on ensuring the supply of drugs and meeting product shortages applies. Whether the MHRA applies these rules to a virtual wholesale dealer has yet to be publicly tested.

6. What is the procedure to appeal (legal remedy) a licensing decision?

If an applicant does not agree with the decision of the Medicines and Healthcare Products Regulatory Agency (MHRA) not to grant a marketing authorisation, their recourse is to an administrative law procedure known as "judicial review". Under this process, the applicant must prove that the way the decision was made was not lawful, for example if the MHRA has failed to take specific information into account that should have been a part of the decision-making process.
7. What are the costs of obtaining licensing?

Fees for obtaining licences are set by the Medicines and Healthcare Products Regulatory Agency (MHRA) and are updated in April every year:

- For 2018 to 2019, the fee for a UK marketing authorisation is GBP92,753.
- For a decentralised application where the UK is the reference member state, it is GBP89,556.

A full list of current fees can be found on the MHRA website (www.gov.uk/government/publications/mhra-fees/current-mhra-fees).

8. What are the different categories of drugs for distribution?

There are three categories of drugs:

- Prescription-only (POM).
- Only from a pharmacy (P).
- On general sale (GSL).

9. Who is authorised to distribute prescription drugs and over-the-counter drugs to consumers?

Prescription drugs

Prescription-only drugs can be prescribed and supplied by:

- A doctor.
- A dentist.
- A supplementary prescriber, although there are conditions and limitations on giving injections (regulation 215, Human Medicines Regulations 2012 (HMRs)).
- A nurse independent prescriber.
- A pharmacist independent prescriber.
- An optometrist independent prescriber (not medicines for injection or controlled drugs).
- A community practitioner nurse prescriber, though there is a list of products that they are allowed to prescribe (schedule 13, HMRs).
- A therapeutic radiographer independent prescriber, except for specials and a list of controlled drugs.
- A podiatrist independent prescriber, except for specials and a list of controlled drugs.
- A paramedic independent prescriber, except for specials and a list of controlled drugs.
- A European Economic Area (EEA) health professional, except for controlled drugs and drugs given by injection (regulation 214, HMRs).

Over-the-counter (OTC) drugs can be supplied or offered for sale or supply on premises that are a registered pharmacy.

There are also provisions in regulation 224 of the HMRs for emergency sales of prescription-only drugs by a licensed pharmacist where a prescription is provided within 72 hours. An emergency supply for a more limited range of prescription-only drugs is possible, at the request of the patient (regulation 225, HMRs).

Over-the-counter drugs

Over-the-counter (OTC) drugs (that is, medicines that are only from a pharmacy (P) or on general sale (GSL)) can be distributed to consumers by any pharmacy registered with the General Pharmaceutical Council. GSL medicines can also be distributed from premises that the occupier can close so as to exclude the public and on the condition that the products are pre-packaged in advance of supply to those premises and supplied in packaging that has not been opened. There are also restrictions on the volume of analgesics packaged and available for general sale (schedule 15, HMRs).

It is unlawful to sell drugs from an automatic machine except for GSL products.

10. What drugs can an attending physician distribute and under what circumstances?

Medicines legislation does not specifically address the issue of the administration of medicines. The restrictions on the sale or supply of prescription-only medicines do not apply to doctors or dentists registered to practise in the UK (and with limitations, the European Economic Area (EEA)) (regulation 223(1), Human Medicines Regulations 2012).

11. Who is authorised to prescribe prescription drugs to consumers?

See Question 9.

12. Is direct mailing/distance selling of drugs permitted in your jurisdiction?

Over-the-counter (OTC) drugs can be sold via internet pharmacies based in the UK.

Conditions

Conditions imposed on distance selling require the sale to be made from lockable premises. All pharmacies, including internet-only pharmacies, must be registered with the General Pharmaceutical Council.
Council (GPhC). The GPhC issues logos to internet sites supplying medicines if they are satisfied that they meet specific criteria, including those in its guidelines relating to the issue of the logo.

Anyone in the UK selling medicines to the public via a website must also be registered with the Medicines and Healthcare Products Regulatory Agency (MHRA) and be on the MHRA’s list of UK registered online retail sellers.

They must also display the new EU common logo on every page of their website offering medicines for sale, even if they display the GPhC voluntary logo. There is then a link from the registered EU common logo on their site to their entry in the MHRA’s list of registered online sellers.

**Cross-border sales**

UK registered pharmacies can supply overseas patients through a UK-based internet pharmacy, subject to receipt of a lawfully issued prescription for prescription-only medicines. There are set requirements for prescriptions that can be lawfully filled by registered pharmacies in the UK (regulations 217 to 218, Human Medicines Regulations 2012 (HMRs)).

**Electronic prescriptions**

There is specific provision covering electronic prescriptions, allowing prescriptions to be transmitted via the internet so that a patient can be dispensed prescription-only medicines through direct mailing. Certain conditions apply, including that the electronic prescription must be signed with an advanced electronic signature and sent to the person by whom it is dispensed either (regulations 219 and 219A, HMRs):

- As an electronic communication (whether or not through one or more intermediaries).
- Via the electronic prescription service.

The electronic prescription service is managed by the Health and Social Care Information Centre established under section 252 of the Health and Social Care Act 2012.

**13. What regulatory authority is responsible for supervising distribution activities?**

The Medicines and Healthcare products Regulatory Agency (MHRA) supervises the distribution of drugs and can choose whether to resolve a matter directly with the individual or to undertake a criminal prosecution under the Human Medicines Regulations 2012 (HMRs), the Trade Marks Act 1994 or the Proceeds of Crime Act 2002. The MHRA can also ask for an injunction to prevent sale or importation. This work is undertaken by the Defective Medicines Report Centre (DMRC), which is a unit of the Enforcement and Intelligence Group of the MHRA that takes action against illegal activities involving medicines and their availability, manufacture, import, sale, supply and administration. Sanctions include criminal prosecutions, which are usually tried in the Crown Court.

**14. What is the procedure to appeal (legal remedy) a distribution decision?**

From the Crown Court, there is an appeal to the Court of Appeal and then the Supreme Court as a second appeal, but only on a point of law.

If the matter is not dealt with in criminal proceedings and the Medicines and Healthcare products Regulatory Agency (MHRA) takes a decision (such as a refusal) that is not accepted by the company, this can be challenged through judicial review of the decision.

**15. What are the legal consequences of non-compliance with consumer distribution laws?**

If an unlicensed drug is distributed or if an unauthorised person distributes drugs, the Medicines and Healthcare products Regulatory Agency (MHRA) requires that all such sales cease and that a recall is put in place for products improperly distributed.

There are criminal penalties (see Question 13) available as well as civil actions by owners of patents, supplementary protection certificates and trade marks if any of these are infringed. These laws allow the rights’ owners to work together with HM Customs and Revenues’ (HMRC) Intellectual Property Authorisation Unit to stop counterfeit medicines at the border.

**16. What is the legal regime regarding wholesale distribution of drugs?**

Any company or individual wishing to wholesale deal drugs within the EU must hold a wholesale dealer’s licence (obtained from a national competent authority) that specifies the premises from which they can undertake their wholesale dealing operations.

Supplying wholesale is defined as selling, supplying or procuring to anyone other than the end-user of the drug, and is permitted where there is a marketing authorisation in place for the product in the UK or other country of the European Economic Area (EEA) in which the wholesale dealer is operating. Applications for wholesale dealers’ licences in the UK are made to the Medicines and Healthcare products Regulatory Agency (MHRA) through its eSubmissions portal. The MHRA publishes the Orange Guide of the Rules and Guidance for Pharmaceutical Manufacturers and Distributors, which applies to the activities of wholesale dealers in the UK.

The holders of product licences have a general duty to ensure appropriate and continued supplies of the product to which the certificate relates to pharmacies and persons authorised to supply the product so that the needs of patients in the UK are met (regulation 118, Human Medicines Regulations 2012). The MHRA has also agreed with industry Guidelines on Best Practice for ensuring the efficient supply and distribution of medicines to patients, last published in January 2013. There is further guidance developed with the Department of Health and the pharmaceutical supply chain, which is the “Trading Medicines for Human Use: Shortages and Supply Chain Obligations”, last updated in January 2013.

**17. What regulatory authority is responsible for supervising wholesale distribution activities?**

**Regulatory authority**

The Medicines and Healthcare products Regulatory Agency (MHRA) Inspection, Enforcement and Standards Division is responsible for supervising wholesale distribution activities and their policy unit advises on the interpretation of the law as well as developing policy relating to wholesale distribution activities.

**Supervision**

The MHRA can revoke, vary or suspend a licence where they find that the wholesaler is not meeting the conditions of the licence.

**Rights of appeal**

The licence holder can make written representations and appear before an adjudicator to request a review of the decision. They also have the right to request judicial review of the MHRA’s decision through the courts.

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18. What are the legal consequences of non-compliance with wholesale distribution laws?

A wholesale dealers' licence whose terms are breached can be revoked, varied or suspended by the Medicines and Healthcare products Regulatory Agency (MHRA).

MARKETING
Promotion

19. What is the general legal regime for the marketing of drugs?

Pharmaceutical advertising is regulated by EU laws that are transposed into and supplemented by UK laws, specifically Part 14, Chapter 2 of the Human Medicines Regulations 2012 (HMRs), while Chapter 3 provides the enforcement regime.

In the EU, it is prohibited to advertise prescription-only drugs. For other drugs, it is prohibited to publish an advertisement unless the advertisement encourages the rational use of the product by presenting it objectively and without exaggerating its properties. Advertisements that are misleading cannot be published. It is a requirement to include a statement indicating:

- Those to whom the advertisement is addressed.
- The method of its publication.
- The date when it was first published.

The Cancer Act 1939 prohibits certain advertisements relating to treatments for cancer.

As well as the legislation that is specific to the advertisement of pharmaceuticals, other more generally applicable laws also apply. These include the Trade Descriptions Act 1968 and the Consumer Protection from Unfair Trading Regulations 2008 that implement the EU directives on misleading and comparative advertising. The Director-General of Fair Trading is the supervisory body and enforcement is carried out at a local level by trading standards. Broadcast advertising is regulated by the Broadcasting Act of 1990 and 1996 and the Communications Act 2003. There are also the general advertising rules laid down by the Advertising Standards Association through the Code of Advertising Practice (CAP) and the Broadcast Code of Advertising Practice (BCAP).

The Bribery Act 2010 must also be taken into account in any interactions with health care professionals by the pharmaceutical industry.

The Medicines and Healthcare products Regulatory Agency (MHRA) publishes a "Blue Guide" to pharmaceutical advertising, currently in its third edition published in December 2014. This contains details of its opinions on the interpretation of pharmaceutical advertising legislation.

Pharmaceutical advertising is largely self-regulated. For prescriptions medicines, the Association of the British Pharmaceutical Industry (ABPI) publishes its code of practice and is administered and regulated by a separate body, the Pharmaceutical Medicines Code of Practice Authority (PMCPA).

For over-the-counter (OTC) medicines, the self-regulatory body is the Proprietary Association of Great Britain (PAGB), which publishes its own codes of practice and reviews all advertising of its members prior to publication.

20. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organisations)?

The Secretary of State for Health has the primary responsibility for supervising marketing activities for pharmaceutical products. This responsibility is delegated to the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA allows self-regulation and maintains relationships with the Association of the British Pharmaceutical Industry (ABPI) and the Proprietary Association of Great Britain (PAGB), but still maintains its own ultimate authority over advertising. The MHRA's role is supervisory for companies that are members of those industry bodies and the MHRA continues to deal directly with companies and individuals that are not either members of the relevant self-regulatory industry bodies or signed up to the relevant codes.

For prescription medicines, the self-regulatory body is the ABPI, which publishes its code of practice and is regulated by the Pharmaceutical Medicines Code of Practice Authority (PMCPA). Members of the ABPI have signed up to the ABPI code, but non-members can also agree to abide by the ABPI code and have their advertising subject to the same regime.

For over-the-counter (OTC) and on general sale (GSL) products advertised to consumers, the PAGB publishes its code of practice and pre-vets all its members' advertising.

Where complaints occur, the MHRA can require that future advertising of the perpetrator is pre-vetted by them. The MHRA also pre-vets advertising for new products whenever it considers it appropriate. They aim to give an opinion within five days from submission.

Marketing to consumers

21. What is the legal regime for marketing to consumers?

Only over-the-counter (OTC) and on general sale (GSL) products can be advertised to consumers, except for government controlled vaccination campaigns. No offers to treat or prescribe any remedy for the treatment of cancer can be made. Medicines containing psychotropic or narcotic substances cannot normally be advertised to the general public.

The following information must be included in advertising addressed to the public:

- Name of the drug.
- If the product contains only one active ingredient, the common name of the drug.
- Information for the product's correct use.
- An express and legible invitation to read carefully the instructions in the leaflet or on the label.
- For products with a traditional herbal registration only, the following statement: "Traditional herbal drug for use in [indications consistent with registration] exclusively based on long standing use as a traditional remedy".

It must also be clear that the material is an advertisement and the product being advertised is a medicine.
22. What kinds of marketing activities are permitted in relation to consumers and the products which may be advertised to them?

There are no restrictions on where advertising of over-the-counter (OTC) drugs can be placed.

The content of advertising for authorised OTC drugs to consumers must not:

- Relate to a drug containing narcotic substances.
- State or imply that a medical consultation or surgery is unnecessary.
- Offer to provide a diagnosis or suggest a treatment by post or electronically.
- By a description or detailed representation of a case history, be likely to lead to erroneous self-diagnosis.
- Suggest that effects of the drug are guaranteed, better than or equivalent to those of another identifiable treatment or product or not accompanied by any adverse reaction.
- Use in terms that are misleading or likely to cause alarm, pictorial representations of changes in the human body caused by disease or injury or the action of the drug on the human body.
- Refer to claims of recovery in terms that are misleading or likely to cause alarm.
- Suggest the health of a person not suffering from any disease or injury could be enhanced by taking the drug.
- Suggest the health of a person could be affected by not taking the drug.
- Suggest the drug is a food, cosmetic or other consumer product.
- Suggest that the drug’s safety or efficacy is due to the fact it is natural.
- Refer to a recommendation by scientists, health care professionals or persons that because of their celebrity could encourage the use of the drug.
- Be directed principally at children.

The advertisement must make it clear it is an advertisement and the product must be clearly identified as a drug.

- Promotions must be for a sufficiently long duration to avoid encouraging over-purchasing unnecessary medicines.
- The promotion must not amount to the drug being provided free of charge.

Similarly, points on loyalty cards must not be excessive in a way that could encourage purchases.

Free gifts are permitted if:

- The gift is of a sufficiently lower value than the price of the medicine (both the actual and perceived value) so as not to encourage purchase of the medicine to get the gift.
- The gift is related to the use of the medicine.
- Consumers are not required to purchase multiple medicines to obtain the gift.
- The gift is not attractive to children.
- The gift is not likely to result in the consumer needing to use more of the medicine.

Offers such as “two for the price of one” are permitted, but consumers must still have the choice of buying a single product. However, it is considered that promotions that encourage people to buy multiple packs of medicines that have known safety issues are undesirable. Any volume promotions relating to drugs must:

- Be intended for medium to long-term use.
- Not contain ingredients that have the potential for misuse or accidental poisoning.

Drug packs must also not be banded together for sale unless that banding is authorised by the Medicines and Healthcare products Regulatory Agency (MHRA).

It is not considered ethical to require consumers to purchase a medicine to enter a prize promotion.

23. Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers (for example, “buy-one-get-one-free”)?

The provision of free samples of drugs to consumers is prohibited (regulation 293, Human Medicines Regulations 2012).

There are no specific restrictions on special offers but promotions that are more likely to encourage or unnecessary use of medicines, and particularly those with known safety issues, are likely to be prohibited. This principle is reflected in the Proprietary Association of Great Britain (PAGB) “Guidelines on Consumer Promotions and Public Relations” (PAGB Guidelines), which provide additional guidance on its application.

The PAGB Guidelines on consumer special offers require that:

- The money off or price reduction should not be excessive.
- The proposed amount of discount or offer must be justified.

Advertising via the internet is subject to the same rules as other consumer advertising of drugs. However, given that advertising via the internet directed at, or available to, UK consumers can be made from anywhere in the world, this poses practical issues for enforcement.

Advertising posted on UK websites or aimed at the UK audience is subject to UK medicines advertising legislation.

24. Are there particular rules of practice on the use of the internet/social media regarding drugs and their advertising?

25. What regulatory authority is responsible for supervising marketing activities to consumers?

Regulatory authority
The Secretary of State for Health retains primary responsibility for supervising marketing activities for pharmaceutical products. Its responsibility is delegated to the Medicines and Healthcare products Regulatory Agency (MHRA).

Supervision
The MHRA allows self-regulation of consumer advertising for over-the-counter (OTC) and general sales list products by the Proprietary Association of Great Britain (PAGB), but retains ultimate authority over advertising. Members of the PAGB must obtain approval for their adverts whatever the media. Clearcast is an additional approval body for TV commercials, the Radio Advertising Clearance Centre (RACC) for radio commercials, and the Cinema Advertising...
Authority (CAA) for advertising in cinemas. The Advertising Standards Authority (ASA) also exercises control over consumer advertising where this is in print, by direct marketing, sales promotions, radio, TV or over the internet. For TV or radio sponsorship, Ofcom acts as the complaint body (as well as the MHRA).

Rights of appeal
There is no right of appeal against the final determination by the MHRA of a breach of consumer advertising laws but the decision can be judicially reviewed through the administrative law process. For PAGB, Clearcast, the RACC and CAA, there is a requirement for prior authorisation for the advertisement. Therefore, any disputes are usually resolved by negotiation before advertising the product.

The ASA takes action post-marketing and there is a 21-day window from the date on the ASA’s letter of notification of the ruling in which the advertiser can ask the Independent Reviewer of the Rulings of the ASA Council to review the case. Cases are only reviewed where there is a substantial and apparent flaw of process or ruling or if additional relevant evidence is available. Decisions can be challenged in the administrative law division of the high court using a judicial review process, but the circumstances for such reviews are limited.

26. What are the legal consequences of non-compliance with consumer marketing laws?

Breaches of the law on pharmaceutical advertising are a criminal offence (regulation 303, Human Medicines Regulations 2012 (HMRs)). Fines can be levied to the statutory maximum and individuals can be imprisoned for up to two years as well as fined. An offence that falls under one of the following regulations is a lesser or “summary offence” that is subject to a fine only:

- Regulation 298(1) of the HMRs (free samples).
- Regulations 299(2) or (3) of the HMRs (medical sales representatives).
- Regulation 300(4) of the HMRs (solicitation or acceptance of inducements or hospitality).

Breaches of the Advertising Standards Authority (ASA) codes are published by the ASA on its website. The ASA can require that advertisers themselves publish in the media a statement noting the breach. Persistent offenders can be required to have some or all of the marketing communications vetted by the Committee of Advertising Practice (CAP) Copy Advice team. Where the breach is online, the CAP can ask internet search engines to remove the company’s paid-for search advertisements from linking to pages hosting non-compliant communication. The ASA can also feature an advertisement drawing attention to the breach.

The effect of the advertisement of the breach of advertising rules can lead to other companies including the media withholding services or denying access to space. Trading privileges (including direct mail discounts) and recognition can be revoked, withdrawn or temporarily withheld. Sometimes, the non-compliant party is referred to Trading Standards that enforces the Consumer Protection from Unfair Trading Regulations 2008, which include criminal sanctions such as fines and imprisonment.

Marketing to professionals

27. What kinds of marketing activities are permitted in relation to professionals?

The law does not prescribe the activities that can be undertaken, but instead covers the restrictions on activities (see Question 28).

28. Are there any restrictions on marketing to professionals?

There are limited legal provisions relating to advertising and marketing to professionals, including various restrictions (regulations 294 to 300, Human Medicines Regulations 2012 (HMRs)).

For advertising to professionals, the Association of the British Pharmaceutical Industry (ABPI) Code applies to prescription-only drugs and the Proprietary Association of Great Britain (PAGB) Professional Code for Medicines applies to over-the-counter (OTC) drugs.

Marketing activities

Promotions cannot be accompanied by written materials, unless the required notices are included as set out in Schedule 30 to the HMRs, as well as the date it was drawn up (regulation 297, HMRs). The information must be accurate, up to date, verifiable and sufficiently complete to enable the recipient to form an opinion of the therapeutic value of the product. Illustrative material must be accurately reproduced and indicate the source.

The provision of unsolicited journal articles is prohibited unless they have been referred (clause 10, ABPI Code).

Free samples can be given to professionals qualified to prescribe them for the purpose of acquiring experience in dealing with that product, in response to a request form signed and dated by the recipient (regulation 298, HMRs). Free samples cannot contain narcotics or psychotropic substances. The sample must be:

- No larger than the smallest presentation available in the UK.
- Marked “free medical sample: not for resale”.
- Accompanied by a copy of the Summary of Product Characteristics (SPCs).

The supplier must maintain an adequate system of control and accountability for its supply of free samples.

Sales representatives can visit prescribers but must provide a copy of the SPC for each product promoted. Any adverse reactions reported to the sales representatives must be reported to the marketing authorisation holder’s scientific service.

Frequency

The provision of samples is (by law) on an exceptional basis only and in any year only a limited number of samples of any particular product can be supplied to an individual prescriber.

The ABPI Code requires “restraint” in the frequency of distribution and volume of promotional material. It also requires non-interventional studies to be conducted for a scientific purpose and properly documented with a protocol. The results of the study must be published in the same way as any clinical trial (section 13, ABPI Code).

Provision of hospitality

Hospitality limited to the main purpose of a meeting is permitted (regulation 300, HMRs) and includes sponsorship for attendance and payment of travel and accommodation expenses.

The ABPI Code requires that hospitality can only be provided to health professionals at scientific or promotional meetings that must be held in appropriate venues "conducive to the main purpose". Hospitality must be limited to subsistence only and cannot be more expensive than what recipients would normally pay for themselves. There is a cap of GBP75 per person excluding VAT and gratuities, but the expectation is that on most occasions sums expended will be significantly lower.

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The PAGB Code includes almost identical provisions, albeit only in relation to meetings for the purpose of advertising and promoting OTC products and without a specific limit on the cost of a meal.

The NHS guidelines on Managing Conflicts of Interest, published in February 2017, requires that its personnel do not accept meals exceeding GBP75 without approval from their manager, and that meals over GBP25 are declared by the individual.

**Gifts to professionals**

Gifts, pecuniary advantages or benefits cannot be supplied, ordered or promised to those that prescribe or supply drugs, unless they are inexpensive and relevant to the practice of medicine or pharmacy (regulation 300(1), HMR). In addition, the NHS guidelines on Managing Conflicts of Interest, requires that its personnel can accept gifts of low-cost branded promotional aids that are less than GBP6 in value.

Clause 18 of the ABPI Code is more restrictive in that it prohibits gifts, pecuniary advantages or benefits to be supplied, offered or promised to health care professionals or other decision makers in connection with the promotion of drugs or as an inducement in relation to drugs.

Exceptions to this are patient support items to be passed to patients as part of a formal patient support programme and that are inexpensive. Inexpensive notebooks, pens and pencils not bearing the names of any medicine can be provided at scientific meetings. If the meeting is organised by the company, these items can bear the company name. If organised by a third party, no company name can be included.

31. **What other items, funding or services are permitted to be provided to professionals?**

**Discounts**

Normal commercial practices are permitted, whereas any practices designed to incentivise professionals to prescribe a particular product rather than the most appropriate one for the patient are prohibited.

**Free samples**

This is the same as for discounts. Items such as samples are permitted, because they are not considered to be incentives. See Question 28.

**Sponsorship of professionals**

See Question 28.

32. **What regulatory authority is responsible for supervising marketing activities regarding professionals?**

**Regulatory authority**

As with consumer advertising, the Medicines and Healthcare products Regulatory Agency (MHRA) has ultimate responsibility for supervising advertising to professionals, with the Pharmaceutical Medicines Code of Practice Authority (PMCPA) supervising self-regulation under the Association of the British Pharmaceutical Industry (ABPI) Code and Proprietary Association of Great Britain (PAGB) supervising self-regulation under the PAGB Code.

However, other activities in relation to professionals, such as sponsorship, hospitality and consultancy arrangements, can also infringe the Bribery Act 2010 and as such, the Serious Fraud Office (SFO) can become involved. The Bribery Act 2010 has extra-territorial effect, which means that activities undertaken in countries outside the UK by companies or individuals with certain connections to the UK can be investigated by the SFO and can lead to criminal prosecution in the UK.

All healthcare professionals with prescribing rights belong to a professional regulatory body. Each of these bodies has its own code of practice. Each one, in one form or another, requires that the professional acts in accordance with the interests of the patient and not in their own interest. Therefore, the health care professional can also be sanctioned in accordance with the rules of their professional body if it is found that their activities with any drug company amounts to an actual or perceived inducement to prescribe.

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Supervision
See above, Regulatory authority.

Rights of appeal

Rights of appeal against MHRA decisions are by way of judicial review through the administrative law division of the High Court.

Decisions of the PMCPA in respect of the ABPI Code are appealed to the Code of Practice Appeal Board.

The SFO can pursue prosecutions through the criminal justice system that are then appealable through the normal court system via the Court of Appeal and the Supreme Court.

33. What are the legal consequences in case of non-compliance with professional marketing laws?

Generally, there are no legal consequences of non-compliance with professional marketing laws, as the UK system is mainly self-regulatory.

However, for breaches of the professional advertising laws, action can be taken by the Medicines and Healthcare products Regulatory Agency (MHRA) for Association of the British Pharmaceutical Industry (ABPI) and Pharmaceutical Medicines Code of Practice Authority (PMCPA) non-members, and the consequences are the same as for breaches of consumer advertising laws (see Question 26). The Advertising Standards Authority (ASA) and other general advertising bodies only deal with consumer advertising and therefore their authority is not engaged for professional advertising.

Breaches of the ABPI Code are considered by the PMCPA Code of Practice Panel. The Panel can require undertakings are given and there is broad scope for what can be included in undertakings, depending on the nature of the breach. This can include undertakings to withdraw particular advertising or cease a particular activity and to take all reasonable steps to prevent a reoccurrence. The undertaking must be signed by the chief executive or managing director. An administrative charge is also levied, calculated on the number of breaches of the ABPI Code that are found.

The Panel can also report a company to the Appeal Board of the PMCPA if the breach is sufficiently serious or raises concerns about a company's procedures. The Appeal Board has additional powers to require audits of company activities, processes and procedures, and can require that marketing materials are pre-vetted. It can also require that the company publishes a corrective statement with the content, timing and placement to be agreed with the Appeal Board. If the breach of the Code is sufficiently serious, the company can be reported to the ABPI board that has the power to suspend or cancel the company's ABPI membership. All cases heard by the PMCPA Panel and Appeal Board are included in publicly available case reports via the PMCPA website.

ENGAGEMENT WITH PATIENT ORGANISATIONS

34. What kinds of activities are permitted in relation to engagement with patient organisations? What are the restrictions that are imposed on relationship with patient organisations?

Interaction with patient organisations is regulated by the general advertising and promotions laws outlined above (see Questions 19 to 28), and otherwise is only separately regulated in detail by clause 27 of the Association of the British Pharmaceutical Industry (ABPI) Code.

Pharmaceutical companies can interact with and support the work of patient organisations, but in doing so must:

- Respect their independence.
- Comply with the prohibition on advertising prescription-only drugs to the public.
- Be transparent about any sponsorship.

All significant work with patient organisations must be the subject of a written agreement that is precise about the relationship, including funding. If the patient organisation is to provide services, they can only be to support health care or research and paid for at fair market value. Companies cannot require exclusivity and must not influence the content of patient organisation material so as to favour its commercial interests.

The requirement for transparency means that a list of patient organisations supported by pharmaceutical companies (updated at least annually) must be publicly available, and must include the amount of financial support and value of non-financial support the organisations receive.

REFORM

35. Are there notable recent developments or regulatory projects in the field of distribution and marketing of drugs?

There are currently no developments planned in the UK for new legislation. It remains to be seen what the outcome of Brexit will mean for the regulation of drugs in the UK, that is, whether the country will continue to follow and apply essentially the current EU provisions or whether it will build a separate body of law.

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Areas of practice. Intellectual property and commercial transactions for life sciences companies; regulation of pharmaceuticals, biotechnology and medical devices; compliance with anti-bribery legislation and applicable codes for life sciences companies.

Non-professional qualifications. LLB Hons, European Legal Studies, Bristol University; Masters in Law and Economics, University of Oxford

Recent transactions

- Advising life sciences companies on interactions with competent authorities where authorisations or certificates have been withdrawn or suspended or are under threat.
- Negotiating a number of in-licences for an oncology company.
- Advising on options available under the orphan drugs regime and its applicability to competitor products.
- Detailed response on ABPI Code relating to an advertising complaint letter from a competitor.
- Advising on nuances of the Pharmaceutical Price Regulation Scheme (PPRS) and statutory scheme.
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Professional associations/memberships

- Chair of the Legal and Compliance Committee of ABHI.
- Member of OBN.
- Member of BIA.