
Lexology Panoramic – Pharmaceutical Antitrust Update

May 2026

1. Pharmaceutical Regulatory Law

i. **Regulatory framework: What is the applicable regulatory framework for the authorisation, pricing and marketing of pharmaceutical products, including biosimilar and generic drugs?**

The Human Medicines Regulations 2012 (HMR) is the principal regulatory framework for medicinal products in the UK, governing the authorisation and commercialisation of medicinal products, including generics and biosimilars.

Following the departure of the UK from the European Union, Northern Ireland occupies an unusual position in the medicines regulatory framework. Nominally, Northern Ireland remains subject to the EU regulatory framework under the terms of the Protocol on Ireland and Northern Ireland to the UK/EU Withdrawal Agreement (Northern Ireland Protocol). However, since 1.1.2025, significant parts of the EU framework have been disapplied in relation to Northern Ireland under Regulation (EU) 2023/1182 and the Windsor Framework (27.02.2023), and centrally authorised marketing authorisations (MAs) issued by the European Commission (the Commission) are not valid in Northern Ireland. In practice therefore the whole of the UK is subject to a single regulatory and authorisation framework for medicines under the HMR, subject to limited exceptions.

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for administering and enforcing the HMR (see further 1(ii) below).

Marketing authorisations

Unless exempt, medicinal products must be licensed under an MA granted by the MHRA before being placed on the market. An MA will only be granted if the applicant demonstrates that the medicinal product meets prescribed quality standards and is safe and effective for the condition for which it is intended. The applicant must provide a dossier of evidence including preclinical and clinical data.

For generic and biosimilar products, an MA may be obtained through an abridged procedure in which the applicant references the preclinical and clinical data submitted to demonstrate the safety and efficacy of an existing medicinal product that is licensed in the UK, subject to evidence demonstrating that the biosimilar or generic meets equivalence standards.

Pursuant to the Windsor Framework, from 1.1.2025, all medicinal products for which an MA is granted fall into two categories:

- **Category 1:** Applies to all medicinal products within the mandatory or optional scope of the EU centrally authorised MA procedure (CAP), conditional marketing authorisations, and generic, hybrid or biosimilar applications based on a Category 1 reference medicinal product.
- **Category 2:** Applies to all medicinal products not in Category 1, including generic, hybrid or biosimilar applications based on a Category 2 reference product.

All MAs granted before 1.1 2025 were assigned to either Category 1 or Category 2 by the MHRA on that date.

Category 1 medicinal products are authorised solely on the basis of UK law. Category 2 medicinal products are authorised on the basis of UK law, but are also subject to the provisions of EU law as specified in Annex 2 of the Northern Ireland Protocol. Among other things, this obliges the MA holder of a Category 2 medicinal product to provide certain information to the European Medicines Agency as well as to the MHRA. The MHRA maintains published lists of MAs in each Category.

Similar to the current EU regulatory framework, regulatory data protection (RDP) in the UK prevents a generic or biosimilar MA applicant from referencing data submitted in support of the first MA for a medicinal product for a period of 8 years. Once RDP has expired, a generic/biosimilar MA applicant can reference such data, but may not place its product on the market for a further period of 2 years. That period of regulatory market exclusivity may be extended by 1 year if the holder of the first MA adds a new therapeutic indication during the period of RDP and this therapeutic indication brings a significant clinical benefit in comparison with existing therapies. From 1.1.2025, only an MA granted in the UK may be referenced in a generic/biosimilar MA application to the MHRA. If the reference MA granted in the UK originated from an MA which was granted in the EU under the CAP before Brexit, then the period of RDP and regulatory market exclusivity for the reference MA will match the EU CAP MA from which it originated.

Similar to the current EU regulatory framework, further types and periods of exclusivity are offered as incentives, including for orphan indications and for completing an agreed Paediatric Investigation Plan.

Under the HMR, each MA includes a summary of product characteristics, a patient information leaflet, and specifications for packaging and labelling. These documents describe the medicinal product, how it should be used, and the indications for which it should be used. An MA holder can only market its medicine for the approved indications, although the MA holder is not obliged to control how its medicine is actually used by end users. In the course of ordinary medical practice, healthcare professionals can and do use medicines for unapproved indications (“off-label” use). However, it is prohibited to promote such use.

All applications for an MA in the UK must be submitted to the MHRA, which under its ordinary national assessment procedure will make a decision on the application within 210 days (excluding clock-stop periods for the applicant to respond to requests for information from the MHRA). A reduced period of 150 days applies to applications for innovative medicines, which include medicines containing a new active substance and all biologic medicines (including ATMPs, vaccines and biosimilars). The MA assessment process can be fast-tracked under specific circumstances, such as public health emergencies or supply shortages.

An International Recognition Procedure (IRP) is also available, under which an applicant that already holds an MA granted by a recognised reference regulator (such as the European Medicines Agency) for the same medicinal product can undergo a MA grant procedure relying on the assessment of the reference regulator. Depending on the procedure, IRP applications will be decided within 60 days, or 110 days with a clock-stop at 70 days for the applicant to respond to requests for information.

Parallel imports licensing

The UK parallel import licensing scheme allows companies to sell medicinal products in the UK that are authorised in an EU or EEA member state, provided that such products are essentially similar to a medicinal product which is authorised under an MA in the UK. A parallel import licence is obtained by application to the MHRA and is valid for 5 years once granted.

A medicinal product may be placed on the market in the UK without an MA where it is subject to a parallel import licence. A parallel import licence does not excuse the holder from compliance with other regulatory requirements under the HMR or other legislation such as the Misuse of Drugs Act 1971.

Marketing

The advertising and marketing of medicines in the UK is subject to the HMR, the MHRA's Blue Guide, the Advertising Standards Authority (ASA) Advertising Codes, and the Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry.

The ABPI Code represents a form of voluntary industry self-regulation. Adherence to the ABPI Code is only mandatory for companies that have become members of the ABPI, although many non-members voluntarily adhere to the ABPI Code, which is widely followed to secure compliance with the HMR and reduce the likelihood of legal enforcement action.

Under the HMR, the Blue Guide, the ASA advertising codes and the ABPI Code, advertising of medicines to the public is prohibited in respect of prescription-only medicines (POM). Advertising is permitted in respect of over-the-counter (OTC) and general sales list-approved medicines, but subject to rules restricting certain promotional practices. Advertising to healthcare professionals is permitted in respect of POMs, subject to strict requirements that prescribe certain mandatory information and restrict the content of advertisements and promotional practices such as incentives, hospitality and gifts. The ABPI Code provides detailed rules and guidance which elaborate on the basic marketing requirements set out in the HMR and the Blue Guide, including as regards comparative advertising and substantiation of claims, and stipulate mandatory internal review and approval procedures for advertising to secure compliance.

Pricing

Pricing of pharmaceutical products in the UK for use in the NHS (or in the HSC in respect of Northern Ireland) is principally addressed through regulations made under the Health and Social Care Act 2012 and regulations made under the National Health Service Act 2006 (NHS Act 2006). Supplies of medicinal products to the private healthcare market in the UK are not subject to pricing regulation.

ii. Regulatory authorities: Which authorities are entrusted with enforcing these rules?

The MHRA is the UK regulator for medicinal products, including the approval of MAs and the marketing and distribution of medicinal products within the UK. It is an executive agency of Department of Health and Social Care (DHSC). Its enforcement tools include the power to enter and inspect premises, seize goods, compel the production of information, and commence criminal proceedings in respect of offences committed under the HMR.

The ABPI is the main trade body for the pharmaceutical industry in the UK. It is responsible for the ABPI Code of Practice (see above). The PMCPA enforces the ABPI Code. The PMCPA does not proactively investigate ABPI Code compliance, but will require a member company or a non-member company that voluntarily adheres to the ABPI Code to respond where a complaint is raised, and determines whether the company's response adequately demonstrates compliance with the ABPI Code. The PMCPA issues public case reports of its determinations.

The ASA also plays a role in relation to advertising of medicinal products by enforcing its Advertising Codes.

The National Institute for Health and Care Excellence (NICE) provides guidance and recommendations as to which medicinal products and other treatments should be available on the NHS in England. The NHS is obliged to fund the use of a medicinal product in accordance with a recommendation issued by NICE. Equivalent organisations exist in Wales (All-Wales Therapeutic and Toxicology Centre) and

Scotland (Scottish Medicines Consortium). The Department of Health in Northern Ireland reviews NICE guidance and recommendations and may adopt them for use in Northern Ireland.

DHSC is responsible for supervising and enforcing pharmaceutical companies' compliance with VPAG and the Statutory Scheme on branded medicines pricing.

The Competition and Markets Authority (CMA) is the principal authority responsible for competition and consumer protection, but does not play a direct role in the regulation of pharmaceuticals.

iii. Pricing: Are drug prices subject to regulatory control?

The nature of pricing controls varies in England, Scotland, Wales and Northern Ireland. This section discusses the approach to pricing in England.

Pricing control as a condition of NICE recommendation

Under the Health and Social Care Act 2012 and the NICE (Constitution and Functions) and NHS England (Information Functions) Regulations 2013, the NHS is obliged to fund medicinal products for which NICE recommendations have been issued. (Products which have not been recommended may still be purchased by the NHS using discretionary budgets.)

NICE is responsible for evaluating whether therapeutic/medicinal products represent value for money for the NHS through technology appraisals. NICE takes into account evidence from expert stakeholders (including MA holders, representatives from industry and the NHS) to evaluate the ratio of quality-adjusted life years (QALY) which the product can deliver to expenditure. This evaluation is based on factors including list price, evidence demonstrating the product's safety and efficacy and the burden on patients of the condition treated by the medicinal product.

Pursuant to a UK-US trade deal on pharmaceutical pricing concluded on 1 December 2025, since April 2026 NICE recommends a medicinal product where the cost of use to the NHS is less than £25,000-£35,000 per QALY delivered by use of the medicinal product.

NICE may also recommend a medicinal product for ultra-rare diseases following another appraisal process for "Highly Specialised Technologies". Under this process, NICE may recommend a medicinal product at a higher threshold of £100,000 per QALY.

Where NICE concludes that a medicinal product will not meet the relevant QALY threshold at the MA holder's list price, the MA holder may enter into a patient access scheme (PAS), under which the MA holder undertakes to provide the medicinal product at a discount to the NHS.

Regulatory control of pricing of branded medicines

Branded medicinal products (including branded generics and biosimilars) and unbranded generic medicinal products are subject to different pricing regimes.

Two regimes control the price of branded medicines used in the NHS: VPAG (a voluntary scheme) and the statutory scheme. Most pharmaceutical companies participate in VPAG as it offers certain incentives not provided by the statutory scheme.

Before launching a new medicinal product, a pharmaceutical company must generally agree a list price (i.e. the maximum supply price to the NHS before customer-specific discounts) with DHSC. Both VPAG and the statutory scheme restrict changes to list prices, including prohibiting list price increases without prior approval from DHSC.

VPAG and the statutory scheme contain affordability mechanisms that allow the NHS to recoup a rebate from pharmaceutical companies where a permitted annual growth is exceeded. The rebate (which is reviewed annually) is calculated as a percentage of eligible sales of branded medicines to the NHS. In 2025, headline rebate rates under VPAG and the statutory scheme reached 22.9% and 23.8% respectively. These figures have now declined, as the headline VPAG rate has been capped at 15%, and the statutory scheme is required to have “broad commercial equivalence” with VPAG, pursuant to the UK-US trade deal on pharmaceutical pricing.

VPAG

VPAG is a non-contractual agreement between DHSC, NHS England and the ABPI, in force from January 2024 to the end of 2028. Suppliers can opt in to the voluntary scheme by application to DHSC.

Under VPAG, the list price of a medicinal product must generally be agreed by the supplier with DHSC upon launch. However, medicinal products that are classified as containing a “*new active substance*” benefit from freedom of list pricing at launch for the first three years after MA grant, provided the price is set “*at a level consistent with securing a positive NICE appraisal*”. Once a list price has been set, VPAG restricts pharmaceutical companies from increasing the list price without prior approval from DHSC.

VPAG incorporates an affordability mechanism, which caps sales of branded medicines to the NHS at an allowed growth rate (3.75% in 2026, increasing to 4% by 2027/2028).

Sales of branded medicines to the NHS which exceed the allowed growth rate are used to calculate a rebate which is paid by VPAG members to the UK government (see above).

Statutory scheme

Companies selling branded medicines that do not opt in to VPAG are subject to the statutory scheme. This is established by s.263 NHS Act 2006 and the Branded Health Service Medicines (Costs) Regulations 2018.

Prices under the statutory scheme are generally capped at a price agreed with DHSC at launch; any increase in list price must be approved by DHSC. There is no automatic right to freedom of pricing for new medicinal products, although the DHSC must take account of new active substances in agreeing the list price at launch.

As under VPAG, pharmaceutical companies must pay an annual rebate to the NHS (see above).

Generic medicinal products

Unbranded generic medicinal products are not regulated by VPAG or the statutory scheme and are generally subject to free pricing.

The reimbursement price for an unbranded generic medicinal product, which is the price at which pharmacists dispensing NHS prescriptions are reimbursed by the UK government, is set out in the NHS Drug Tariff.

Reimbursement prices are revised every month by NHS Prescription Services based on sales data from importers/distributors of medicinal products. The methodology for calculating reimbursement prices differs depending on the part of the NHS Drug Tariff in which a product is listed, which in turn depends on the extent of the product's availability on the market.

iv. **Distribution: Is the distribution of pharmaceutical products subject to a specific framework or legislation? Do the rules differ depending on the distribution channel?**

Unless exempt, a medicinal product must be the subject of an MA granted by the MHRA before it can be placed on the market in the United Kingdom.

Key exemptions from the requirement for an MA are:

- imports from the EU/EEA of medicinal products which are “essentially the same” as another medicinal product the subject of an MA in the United Kingdom, in accordance with a parallel import licence.
- medicines for “special” (i.e. compassionate) use.
- investigational medicinal products for use in a clinical trial, subject to compliance with the Medicines for Human Use (Clinical Trials) Regulations 2004.

Manufacturing of a medicinal product, or importation other than from an “approved country for import”, is prohibited unless authorised by a Manufacturer’s Authorisation (MfA). Wholesale distribution of a medicinal product (or importation from an “approved country for import”) is prohibited unless authorised by a Wholesale Dealer’s Authorisation (WDA). Other activities relating to the sale/purchase of medicinal products that consist of independent negotiation, without physical handling of medicinal products, are prohibited unless performed by an entity registered with the MHRA as a broker under the HMR.

Further licences are required to handle or deal in any medicinal products which are classified as controlled drugs under the Misuse of Drugs Act 1971 or the Misuse of Drugs Regulations 2001.

Distribution of medicinal products

The MHRA supervises and authorises the manufacturing, importation, wholesale distribution and brokering of medicinal products. Companies must apply for necessary licences, which set out the conditions applicable to their activities, including the authorised location. A holder of an MfA, WDA or broker’s registration must comply with specified standards of Good Distribution Practice (GDP) for relating to wholesale dealing. A holder of an MfA must comply with specified standards of Good Manufacturing Practice (GMP) for activities relating to manufacturing and importation. The MHRA audits licence-holders against these standards and may revoke, vary or suspend a licence if it finds that the holder is not complying with the conditions of the licence or applicable GDP/GMP standards.

Sale or supply of a medicinal product to the general public (i.e. retail supply) does not require a WDA, MfA or broker’s registration. However, retail supply of medicines may only be done by a person lawfully conducting a retail pharmacy business which is registered with the General Pharmaceutical Council under the Medicines Act 1968. Medicines designated as “prescription-only” may only be dispensed by a retail pharmacy pursuant to a lawful prescription issued by one of the healthcare practitioners listed in the HMR. Exceptions apply for supply and administration of medicines by healthcare professionals to patients under their care.

v. Intersection with competition law: Which aspects of the regulatory framework are most directly relevant to the application of competition law to the pharmaceutical sector?

Rules on the marketing of medicinal products has been a key area of focus for the competition authorities in recent years. In a number of cases, competition authorities including the CMA have treated comparative marketing claims made by pharmaceutical companies about competitors’ medicinal products as an abuse of a dominant position, where these claims have disparaged the competitor’s medicinal product in a way which is misleading and unsubstantiated. See, for example:

- **Vifor:** CMA investigation into disparaging statements about a competitor. Such statements would ordinarily be dealt with in the UK by the MHRA under the HMR or the PMCPA under the ABPI Code,

and the CMA's decision directly referenced relevant provisions of the HMR and the ABPI Code. Vifor gave commitments and the investigation was closed in 2025.

- **Teva:** Commission investigation for conduct including “systematically disparaging” a medicinal product competing with Copaxone, Teva's multiple sclerosis treatment. This involved spreading misleading information about the safety, efficacy and therapeutic equivalence of the competitor medicinal product with Copaxone to discourage use of the competitor product by healthcare professionals. The Commission fined Teva €462.6 million in October 2024 (subject to appeal).

Competition authorities have also investigated excessive pricing of unbranded generics (which are not subject to regulation under VPAG or the statutory scheme) and abuse of patent rights and anti-competitive settlement agreements to delay the entry of generic medicinal products into the market (so-called “pay for delay”, discussed further below).

2. Competition Legislation and Regulation

i. Legislation and enforcement authorities: What are the main competition law provisions and which authorities are responsible for enforcing them?

UK competition law is primarily governed by two statutes: the Competition Act 1998 (CA98) and the Enterprise Act 2002 (EA02). These laws (as amended) establish the main prohibitions on anti-competitive conduct and set out how mergers are assessed in the UK. In addition, Criminal sanctions can be imposed under the EA02 for individuals involved in cartel activity. Additionally, directors found responsible for such breaches may face disqualification for a specified period under the Company Directors Disqualification Act 1986 (CDDA)

The Competition and Markets Authority (CMA) is the principal authority responsible for enforcing UK competition law in the pharmaceutical sector. The MHRA does not enforce competition law although its procedures may provide relevant background to competition law enforcement.

1. CA98

Anti-competitive agreements (Chapter I prohibition)

CA98 prohibits agreements and concerted practices between businesses, as well as decisions by associations of businesses, that have the object or effect of preventing, restricting or distorting competition. The Chapter I prohibition applies to agreements between competitors and non-competitors. Examples of prohibited conduct include price fixing, resale price maintenance, limiting production and market sharing.

Any agreement that infringes the Chapter I prohibition is void and unenforceable, and the parties may face fines of up to 10% of global group turnover.

Conduct by dominant parties (Chapter II prohibition)

CA98 also prohibits the abuse of a dominant position by one or more businesses. The types of abusive conduct are not limited by statute and have evolved through case law. However, examples include predatory or excessive pricing, refusal to supply access to essential inputs or infrastructure and exclusive dealing arrangements.

Parties found to infringe the Chapter II prohibition may be fined up to 10% of their global group turnover.

2. EA02

The EA02 sets out the UK's merger control regime, including:

- Jurisdictional thresholds determining whether the CMA may review a merger, and
- The substantive assessment used to evaluate whether a transaction may result in a substantial lessening of competition.

The EA02 also provides the legislative basis for the CMA's wider functions, including its power to conduct market studies/investigations.

ii. **Public enforcement and remedies: What actions can competition authorities take to tackle anticompetitive conduct or agreements in the pharmaceutical sector and what remedies can they impose?**

1. **Investigatory actions by the CMA**

The CMA has wide powers to detect and investigate suspected infringements:

- **Investigations:** the CMA can carry out investigations into the conduct of one or more parties for potential infringements of the Chapter I or II prohibitions. Competitor complaints, whistleblowing by current/former employees, and information from merger reviews, other regulators or the public domain can all lead to an investigation.
- **Dawn raids and requests for information:** the CMA can (i) conduct dawn raids (unannounced inspections of business and, in certain circumstances, home premises), (ii) issue compulsory information requests and (iii) require key personnel (including from third parties) to attend interviews.
- **Market studies and sector inquiries:** the CMA can instigate sector-wide investigations to assess any structural or behavioural issues restricting competition.
- **Merger control:** the CMA and authorities across Europe have subjected pharmaceutical mergers to intensive scrutiny, intervening more frequently in this sector than in most others. In the last 10 years the CMA has opened 10 merger investigations in the sector and, during the period prior to Brexit, reviews of pharmaceutical mergers conducted by the Commission were also relevant to the UK market.

The pharmaceutical sector has remained an enforcement priority since the Commission's inquiry into the sector in 2007-2009. In the UK, the CMA has opened 10 CA98 investigations in the sector since 2016 leading to a number of infringement decisions, including issuing fines of more than £430m (some fines were subsequently reduced on appeal).

2. **Remedies competition authorities can impose**

- **Financial penalties:** The CMA typically uses a starting point of 21-30% of a party's relevant turnover (i.e. turnover relating to the product or service that is the focus of the investigation) for the most serious types of infringement of the Chapter I and II prohibitions. Penalties are subject to a cap of 10% of a party's global group turnover. The CMA has in recent years issued a number of substantial fines to companies in the pharmaceutical sector, e.g. fines totalling £260m in [Hydrocortisone](#). Fines may be imposed on parent companies and investors where they form part of a single undertaking with the business under investigation. For example, in [Liothyronine](#) the CMA held private equity investors jointly and severally liable for the infringement and imposed fines of £60.5m.
- **Director disqualification:** Under the CDDA the CMA can seek a court order disqualifying any director of a company that has infringed competition law for up to 15 years. As part of its assessment the court must consider whether the conduct of the individual makes them unfit to manage a company, including their contribution to, or awareness of, the infringement. The CMA can alternatively accept an undertaking from a director in lieu of applying for an order. Over the past 10 years, the CMA has

routinely used this power in the majority of investigations, including in investigations concerning the pharmaceutical sector (for example, the [Fludrocortisone](#), and [Nortriptyline](#) cases).

- Behavioural remedies: Following an infringement decision the CMA will require companies to take steps to bring the infringement to an end. For example, in [Phenytoin](#) the CMA required Pfizer and Flynn to reduce list and supply prices and notify the CMA of any price changes for the 10 years following the decision.
- Behavioural remedies can also include ending exclusionary agreements or abusive pricing strategies, ensuring requisite access to essential inputs or technical information and providing undertakings not to repeat certain conduct.
- Commitments: The CMA may settle investigations on the basis of formal commitments provided by the company under investigation. For example, in an investigation into the supply of lithium carbonate medicines, [the CMA accepted commitments](#) from Essential Pharma which included ensuring the ongoing supply of the medicine at an agreed price with the DHSC. Commitments are subject to review by an independent monitoring trustee.
- Interim measures: Although rarely used, the CMA can impose temporary binding orders or directions on a company to prevent significant damage to a person or category of persons or to protect the public interest.

iii. **Private enforcement and remedies: Can remedies be sought through private enforcement by a party that claims to have suffered harm from anticompetitive conduct or agreements implemented by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?**

A party harmed by anti-competitive behaviour or agreements may bring a private claim in court. Claims may be commenced in the High Court of England and Wales, the Court of Session in Scotland or the CAT. The action can be pursued either as a follow-on (see below), a stand-alone claim, or both.

In a follow-on claim, the claimant relies on an infringement that has already been established by a competition authority, meaning the claimant only needs to demonstrate the loss they have suffered and that it was caused by the infringing conduct. In the UK, this includes claims following on from CMA decisions; subject to limitation, cases may be founded on pre-Brexit decisions of the Commission (for example, claims brought by the NHS in reliance on Commission decisions against [Servier](#) and [Lundbeck](#)).

In a stand-alone claim, the claimant alleges that unlawful conduct occurred without relying on a prior infringement decision, and therefore must prove both that the infringement took place and that it caused them harm (as well as the value of their loss). Some claims comprise mixed follow-on and stand-alone allegations.

Collective actions, brought by a class representative on behalf of a class of claimants/consumers on an opt-out or opt-in basis, have grown in number in the UK over the last decade. However, collective actions on behalf of consumers are unlikely in relation to prescription pharmaceuticals, where the NHS is the primary payer, with consumers paying a flat prescription charge.

Typical remedies available through private enforcement include compensatory damages and injunctions. Interim relief can be sought in appropriate cases (e.g., [Chemistree v Abbvie](#) (2013): application for an interim injunction to mandate continued supply, although the application failed on the facts). For claims (other than collective actions) arising after 1.1.25, exemplary damages are in principle available (s.126, Digital Markets, Competition and Consumers Act 2024).

iv. Sector inquiries: Can the antitrust authority conduct sector-wide inquiries? If so, have such inquiries ever been conducted into the pharmaceutical sector and, if so, what was the main outcome?

The CMA has powers to launch market studies/investigations in response to concerns that the behavioural or structural features of a market are limiting competition.

The most influential market review covering the pharmaceutical sector in the UK remains the [Commission's 2009 pharmaceutical inquiry](#), conducted when the UK was still an EU member. The Commission investigated delays in generic entry, patent strategies, patent settlements ("pay-for-delay"), and the functioning of the regulatory environment. The Commission monitored patent settlement agreements for seven years following the inquiry. The CMA and its predecessor (the Office of Fair Trading) have also conducted market studies into medicines distribution (2007-08), medicine shortages (2015) and various healthcare markets.

v. Health authority involvement: To what extent do health authorities or regulatory bodies play a role in the application of competition law to the pharmaceutical sector? How do these authorities interact with the relevant competition authority?

Although health authorities/regulatory bodies do not directly enforce competition law, the DHSC is known to have previously raised concerns with the CMA about possible anti-competitive conduct by parties supplying pharmaceutical products to the NHS. This has led to the CMA opening investigations into the pricing of Phenytoin and the planned withdrawal of [Priadel](#). During such investigations the DHSC works closely with the CMA to provide it with necessary information for its investigation.

vi. NGO involvement: To what extent do non-government groups play a role in the application of competition law to the pharmaceutical sector?

Non-government groups such as patient bodies and industry associations may complain to the CMA about suspected anti-competitive conduct. They are free to respond to market investigations or public consultations. In some cases, NGOs may intervene directly in infringement proceedings.

3. Review of Mergers

i. Thresholds and triggers: What are the relevant thresholds for the review of mergers in the pharmaceutical sector?

Transactions may be subject to merger control under the EA02 and/or review under the National Security and Investment Act 2021 (NSIA).

EA02

There are no pharmaceutical market-specific jurisdictional thresholds. The CMA has jurisdiction over mergers where:

- UK turnover of the target exceeds £100m; or
 - The transaction leads to the creation or strengthening of a share of supply of at least 25% of goods or services of some description in the UK or a substantial part of it; or
- ii. One party has UK turnover of at least £350 million and a 33% share of supply in the UK (or a substantial part of it) and another party has a UK nexus (i.e. supplies goods or services in the UK or is carried out by a UK person or entity).**

The share of supply test is not a market share test and is not based on economic assessment. The CMA has broad discretion to determine what constitutes an appropriate description of goods/ services for the purposes of the test and therefore to determine its own jurisdiction. In [Roche Holdings /Spark Therapeutics](#) the CMA found that the 25% share of supply was met even though the target (Spark) did not supply products in the UK or generate UK turnover on the basis that Spark had employees engaged in R&D as well as patenting activities in the UK.

A statutory de minimis exception applies automatically where both party's UK turnover is £10 million or less. Alternatively, CMA guidance indicates that it may treat a merger as de minimis where the aggregate annual value of all UK markets concerned is less than £30 million.

Advance notification of mergers to the CMA is, in principle, voluntary since parties may complete transactions without notification. However, the CMA carefully reviews merger activity affecting the UK and mergers that risk or even appear to risk giving rise to a substantial lessening of competition (SLC) in the UK are likely to be called-in for investigation. This may occur up to four months after the public announcement of the merger or the CMA being informed of the relevant facts (whichever is later). When investigating a completed merger, the CMA routinely issues "standstill" initial enforcement orders (IEOs) (and may do so in other cases). The CMA's standard-form IEO prohibits not only completion of the merger but all material changes to the merging businesses (acquirer and target) as well as exchanges of confidential information, subject to burdensome applications for exceptions. The CMA also has the power to unwind mergers that result in a SLC. The voluntary nature of the regime should not therefore be interpreted as meaning that there is no risk in completing with mergers potentially resulting in substantive issues without informing the CMA in advance.

NSIA

The NSIA established a separate regime allowing the government to intervene on grounds of national security in transactions resulting in a change of control. This includes a mandatory notification requirement for transactions in 17 specified priority sectors. Notifications under the NSIA are made to the Investment Security Unit, within the UK Cabinet Office, and not to the CMA.

The sector most likely to be relevant in the context of pharmaceutical mergers is synthetic biology, which includes, among other things, gene editing, engineered cells and enzymes, and biological computing. The government has published [guidance on the scope of the 17 priority sectors](#). In March 2026, the [government announced](#) that guidance for the synthetic biology sector would be refined to increase clarity. Legislation to implement this changes is due to be put before Parliament in 2026.

iii. **Thresholds and triggers: Is the acquisition of one or more patents or licences subject to merger notification? If so, when would that be the case?**

EA02

For a transaction to qualify as a merger it must lead to a change of control resulting in two or more "enterprises" ceasing to be distinct. The lowest level of control is material influence which may in some circumstance be acquired via shareholdings of little over 15%.

An enterprise is defined as the "activities, or part of the activities, of a business". This is a question of fact. However, bare assets, including intellectual property rights (IPRs), will not generally qualify as the activities or part of the activities of a business unless existing or expected revenue is directly attributable to them. CMA [Guidance on Jurisdiction and Procedure \(CMA02\)](#), paragraph 4.11, states:

"intangible assets such as intellectual property rights (including know-how) are unlikely, on their own, to constitute an enterprise unless it is possible to identify recently-generated turnover directly related to the

transferred intangible assets (or expected revenues directly related to the assets being transferred without material further development)."

In [Theramex / Viatris](#) the CMA decided that an asset purchase agreement gave rise to a merger situation where the transfer included commercialisation rights for products that were already available on the UK market. Conversely, in [CSL Behring / uniQure Biopharma](#) a commercialisation/licensing agreement for a treatment in Phase 3 clinical trials was found not to qualify.

NSIA

For a transaction to qualify for mandatory notification under the NSIA, it must involve either:

- an increase in shareholding or voting rights from (i) below 25% to more than 25% (ii) below 50% to more than 50% or (iii) below 75% to more than 75%; or
- acquisition of voting rights that enable the holder to secure or prevent the passage of any class of resolution governing the affairs of the entity.

iv. Market definition: How are the product and geographic markets typically defined in the pharmaceutical sector?

The CMA has historically taken a similar approach to the Commission in market definition, including taking relevant Commission precedent into account. Both authorities recognise that pharmaceutical markets have unique traits that can affect market definition.

Product Market

Pharmaceutical product markets are characterised by a complex demand-side and intense supply-side competition. Demand is typically led by physician prescribing practices, but patients, the NHS and insurance schemes (for private healthcare) may also be relevant. On the supply side, competition exists both between originators and between originators and generic manufacturers. The CMA generally focuses primarily on demand side substitutability.

The precise approach is likely to depend on the regulatory status of the products at issue, in particular whether they are available as POMs only or OTC, see e.g., [Actavis/Auden](#).

For POM, the CMA typically takes account of the Anatomical Therapeutic Classification (ATC) system of the European Pharmaceutical Marketing Association. Formally this has four levels:

- ATC1: main anatomical groups
- ATC2: a pharmacological or therapeutic group
- ATC3: therapeutic indication (i.e. its intended use)
- ATC4: mode of action.

Below this, products may be classified by the specific molecule/active substance (so-called "ATC5"). In practice, merger assessments will likely consider at least levels ATC3, ATC4 and ATC5 to the extent there is any overlap between the parties' activities at each level. In [Actavis/Auden](#), the CMA examined markets based on different strengths and/or galenic forms below ATC5. The CMA has also defined markets below ATC5 in non-merger cases, e.g., [Phenytoin](#).

For OTC medicines, purchase decisions are taken by consumers rather than physicians, so branding, advertising, labelled indication, format and price may be more relevant than active ingredients, see e.g.

the EC acknowledgment of the importance of brand recognition in *Sanofi/Boehringer Ingelheim Consumer Healthcare* ([Case M.7919](#)). In *Actavis/Auden* the CMA assessed branded and non-branded medicines as part of the same frame of reference, but noted that brand loyalty might limit switching and higher-priced originator products may represent weaker constraints on generic counterparts.

Geographic Market

The geographic market for existing pharmaceutical products is generally national in scope, see e.g., *Roche Holdings / Spark Therapeutics*:

“the relevant geographic frame of reference should be national in scope, on the basis of national regulatory schemes for authorising and reimbursing treatments, prescribing practices, pricing policies and marketing strategies used by pharmaceutical firms which differ across jurisdictions”

For pipeline products, however, the CMA is likely to take account of constraints from products in development globally, see e.g., *AstraZeneca/Alexion*.

v. Sector-specific considerations: Are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

Many sector specific factors are taken into account in the CMA's approach to market definition. In addition, the CMA's [Merger Assessment Guidelines](#) (CMA129) make clear that for products in development, account will be taken of the regulatory steps and time needed to bring products to market, see similarly *Roche Holdings /Spark Therapeutics*.

vi. Addressing competition concerns: Can merging parties put forward arguments based on the strengthening of the local or regional research and development activities, efficiency-based arguments, or other pro-competitive evidence to address antitrust concerns?

Where the CMA identifies a possible SLC, merging parties can submit evidence of efficiencies and/or customer benefits. However, the requirements are stringent: efficiencies must be strongly evidenced, merger-specific, rivalry-enhancing, *“timely, likely and sufficient”* and must benefit UK consumers. Relevant efficiencies in the pharmaceutical sector may include improved or accelerated R&D, cost savings from pooling scientific capabilities, or an increased incentive to innovate. Relevant customer benefits may include product improvements, including in markets not affected by the SLC, even if they do not prevent an SLC arising.

Existing CMA Merger Assessment Guidelines (CMA129) make clear that *“it is uncommon for a merger to be cleared on the basis of countervailing factors alone”*. However, the CMA is [currently reviewing](#) its approach to merger efficiencies with any changes to be implemented by summer 2026.

vii. Horizontal mergers: Under which circumstances will a horizontal merger of companies currently active in the same product and geographic markets be considered problematic?

Horizontal mergers take place between direct competitors and so inevitably result in the removal of a market participant. They are therefore often the most problematic from a competition law perspective. This can be exacerbated, in the pharmaceutical sector, by narrow market definitions resulting in a small number of participants with high market shares.

The CMA will examine whether a horizontal merger leads to an SLC as a result of either:

- Unilateral effects – where the loss of competition between the merging parties allows the merged entity, acting alone, to increase prices, reduce quality, quantity of supply or innovation efforts. The risk of unilateral effects will generally be higher the closer the competition between the merging parties products.
- Co-ordinated effects – where the reduced number of competitors on the markets leads to collusion (on pricing or other parameters) between remaining participants. It is typically easier to coordinate in stable, settled economic environments with few suppliers. Pharmaceutical competition is often dynamic, innovation driven and complex. However, concerns may arise in mature and/or genericised markets dominated by a small number of companies.

In [Theramex/Viatris](#) the CMA concluded that the merger resulted in an SLC as a result of unilateral effects in the hormone replacement therapy (HRT) market. In the UK market for systemic HRT, the parties would have a combined share of around 75-90%.

viii. Product overlap: When is an overlap with respect to products that are being developed likely to be problematic? How is potential competition assessed?

The CMA considers potential competition to be an important driver of innovation. It is likely to carefully examine any merger between parties with rival products in development (pipeline products). Overlaps in pipeline products may be problematic where the products would be close competitors, e.g. if they target the same indication or are likely to be substitutable, particularly when they approach the final stages of the pre-launch process and alternatives are limited, see e.g. [Theramex/Viatris](#). In assessing potential competition between pipeline products, the CMA is likely to place greater weight on forward-looking contemporaneous evidence, including projections, than on historical performance, see e.g. [Roche/Spark](#). The CMA's Merger Assessment Guidelines (CMA129) stress that it will also consider the risk of foreclosure from reprioritisation of R&D spend or restrictive licensing as a result of the merger.

ix. Remedies: Which remedies will typically be required to resolve any competition issues that have been identified?

Traditionally the CMA has strongly preferred structural remedies (e.g. sale of a business) to behavioural remedies, which do not replace the lost market participant, can distort competition and are often difficult to monitor. This has been particular true at phase 1 where the CMA will accept a remedy only if satisfied that it is clear-cut, capable of ready implementation resolves all identified competition concerns.

However, in the CMA's updated [Merger Remedies guidance](#) (December 2025, CMA87) the CMA notes "*behavioural remedies can be effective in some places*" and no longer includes an express presumption against behavioural remedies at phase 1. Behavioural remedies may therefore feature more prominently in future CMA decisions.

Where structural remedies are required, the divestment package must enable the business to compete effectively. It may therefore need to include access to relevant intellectual property rights (patents, trademarks), marketing authorisations, clinical data, price approvals, and manufacturing and supply agreements (see, e.g. [Theramex/Viatris](#)). If a pipeline product is divested, the package may also need to include R&D capabilities, data or ongoing support to bring the product to market.

4. Anticompetitive Agreements

i. Assessment framework: What is the general framework for assessing whether an agreement or concerted practice can be considered anticompetitive?

In the UK, the prohibition in CA98, Chapter I (Chapter I prohibition) applies to agreements, decisions or concerted practices (Agreements) between independent undertakings that have as their object or effect an appreciable restriction of competition that may affect trade in the UK. The prohibition also applies to Agreements implemented outside the UK which are capable of having a foreseeable effect on UK trade.

The Chapter I prohibition is analogous to Article 101 of the Treaty on the Functioning of the European Union (TFEU) and – although since 31.12.2020 EU law no longer applies directly in the UK to agreements and conduct due to Brexit – analysis of Agreements continues to be strongly influenced by the case law of the Court of Justice of the EU (CJEU) and the decision-making practice of the Commission. S.60A CA98 requires decision-makers to seek to maintain consistency with pre-Brexit EU case law, subject to a series of exceptions.

Agreements that restrict competition can be exempt from the Chapter I prohibition in one of two ways:

- a) the Agreement satisfies the criteria for an individual exemption under s.9 CA98

Agreements that improve production or distribution, or promote technical or economic progress while allowing consumers a fair share of the resulting benefit are exempt from the Chapter I prohibition. Exemptions under s.9 CA98 are subject to individual assessment and require careful consideration by the parties involved.

- b) the Agreement qualifies for a UK block exemption

Block exemptions set out criteria which, if satisfied, provide a safe harbour for Agreements that otherwise infringe competition law. The CMA retains the ability to cancel the application of a block exemption to a particular Agreement. Parties must self-assess to determine whether an Agreement can receive the benefit of a block exemption. In the UK there are four main block exemptions:

[CA98 \(Vertical Agreements Block Exemption\) Order 2022 \(VABEO\)](#)

Available for vertical Agreements (i.e. between businesses operating at different levels of the supply chain) where neither party exceeds a 30% market share, provided there are no hardcore restrictions such as price fixing or market sharing. Certain restraints such as non-compete obligations are considered excluded restrictions and must be individually assessed for their compliance with competition law. The CMA has issued guidance on the application of VABEO: [CMA166 \(July 2022\)](#).

[CA98 \(Technology Transfer Block Exemption\) Order 2026 \(TTBEO\)](#)

The TTBEO applies to licences of technology (including patents, know-how and software copyright), between competitors and non-competitors. See further below.

[CA98 \(Research & Development Agreements Block Exemption\) Order 2022 \(R&DBE\)](#)

The R&DBE applies to horizontal Agreements between competitors/potential competitors. The exemption is available for joint R&D and joint exploitation of the results (e.g. through production or licensing), up to a combined market share of 25%, and provided there are no hardcore restrictions. Certain excluded restrictions are also not covered under the R&DBE, e.g. an obligation not to grant a production licence to a third party, and must be individually assessed.

[CA98 \(Specialisation Agreements Block Exemption\) Order 2022 \(SABEO\)](#)

The SABEO applies has similar requirements and structure to the R&DBE and covers unilateral, reciprocal and joint production agreements under which one or more parties cease/ limit production of certain goods/services and instead obtain them from/produce them with, another party.

The CMA has issued guidance on horizontal agreements (including both R&D and specialisation agreements): [CMA184 \(August 2023\)](#).

Outside of the block exemptions, agreements may also benefit from the de minimis exception where and there are no hardcore restrictions (see CMA184, paragraphs 3.55-3.59).

ii. Technology licensing agreements: To what extent are technology licensing agreements considered anticompetitive?

Licensing agreements, whilst typically procompetitive in nature, can have anticompetitive effects. Technology transfer agreements (licences to patents, know-how, etc) can for example include output or end-use restrictions that may be necessary for an agreement to be concluded but may also be deemed to affect competition.

Post-Brexit, the EU's Technology Transfer Block Exemption Regulation (EUR 2014/316) (TTBER) was assimilated into UK law and exempted certain technology agreements from the Chapter I prohibition. EU Regulation 2014/316 expired on 30.4.2026 and on 1.5.2026, the TTBER replaced the assimilated TTBER.

Under the TTBER, technology transfer licences are exempt provided market share thresholds are not exceeded (20% combined share for competitors and 30% per party for non-competitors), and the licence contains no hardcore restrictions. Excluded restrictions require separate assessment.

The CMA intends to publish guidance on technology transfer agreements. Pending publication, the equivalent Commission guidance (2026/C 2842) is useful.

iii. Co-promotion and co-marketing agreements: To what extent are co-promotion and co-marketing agreements considered anticompetitive?

In principle, pharmaceutical companies can sell the same drug separately (co-marketing) or together, marketing a drug under one name (co-promotion). Such agreements can facilitate efficient promotion of new medicines, facilitate entry into new geographic/therapeutic markets, or allow parties to combine marketing expertise.

The legality of co-promotion and co-marketing agreements is fact-specific. Competition concerns can arise if such agreements lead to co-ordination between competitors, particularly where the agreement involves exchanging commercially sensitive data such as future pricing, strategy information, product volumes etc. The CMA has not considered co-promotion or co-marketing agreements has not provided specific guidance on such agreements. However, the Commission previously imposed fines for use of a co-promotion agreement as part of a broader strategy to delay generic entry ([Case AT.39685 – Fentanyl](#)).

iv. Other agreements: What other forms of agreement with a competitor are likely to be an issue? How can these issues be resolved?

Following the Commission's pharmaceutical sector inquiry, there was a focus on "pay-for-delay" patent settlement agreements.

The CMA has taken action in relation to other types of competitor agreements in the pharmaceutical sector. For example, the CMA has issued fines for market-sharing and information exchange (Nortriptyline) and has investigated a number of other agreements.

The CMA has also provided guidance on competitor collaborations for combination therapies ([Prioritisation Statement on Combination Therapies \(17.11.2023\)](#) confirming it will not prioritise investigations into such collaborations).

v. Issues with vertical agreements: Which aspects of vertical agreements are most likely to raise antitrust concerns?

Resale Price Maintenance (RPM)

Agreements that fix or indirectly control downstream resale prices are hardcore restrictions under UK law. RPM can arise in the supply of branded medicines, or schemes that limit discounting to the NHS, pharmacies, or private healthcare providers. The [CMA's vertical restraints guidance \(CMA166\)](#) indicates that for fulfilment contracts – where a supplier has agreed a sale with a specific customer and then appoints a third party to carry out that sale – RPM is not automatically illegal. Conversely if the customer chooses who will fulfil the contract then imposing a fixed price can restrict competition.

Exclusivity and non-compete obligations

Supply or distribution agreements that require distributors, pharmacies or hospitals to source exclusively from a single manufacturer or otherwise restrict their ability to stock a competing product can result in foreclosure where the supplier has market power. Such restrictions reduce consumer choice and create barriers to entry.

Restrictions on parallel trade

Clauses that limit a distributors' autonomy to decide where products can be sold, restrict exports, or otherwise deter parallel imports within the UK or EU can infringe competition law. Parallel imports play an important role in price moderation in the pharmaceutical sector.

Restrictions on passive sales

Preventing distributors from responding to unsolicited orders from outside their allocated territory, particularly through online orders, or customer group are typically treated as hardcore restrictions.

Dual distribution

Where a manufacturer competes downstream with its independent distributors, it may gain access to commercially sensitive information or be able to favour its own downstream business. CMA guidance on vertical restraints (CMA 166) sets out non-exhaustive examples of information exchange in a dual distribution model. Sharing of information necessary to implement the agreement (e.g. technical information about contract products or logistical information) is unlikely to restrict competition. Conversely information about future pricing or commercial strategy is likely to restrict competition by object.

vi. Patent dispute settlements: To what extent can the settlement of a patent dispute expose the parties concerned to liability for an antitrust violation?

Patent settlement agreements that involve a specific type of value transfer from an originator company to a generic company can give rise to competition concerns. A value transfer can be monetary or some other indirect financial benefit, such as entry into a distribution agreement or licence grant.

The CMA has issued significant fines for 'pay-for-delay' agreements, both in the context of patent settlements and where no settlement was involved:

- **Paroxetine (2016):** [£45m fine](#) (reduced on appeal) imposed on GSK and various generic manufacturers for settlement agreements that protected GSK's monopoly position. The CMA held that GSK also abused a dominant position by making cash payments and other value transfers to induce potential competitors to delay independent entry to the UK market.
- **Fludrocortisone (2020):** two companies agreed to stay out of the fludrocortisone market to enable Aspen to maintain its position as the sole UK supplier.

vii. Joint communications and lobbying: To what extent can joint communications or lobbying actions be anticompetitive?

Joint communications and lobbying are not inherently problematic under competition law; competing business may have legitimate reasons to jointly seek to influence policy. A trade association or similar body may be an appropriate vehicle through which to advocate a particular joint position. However, such conduct may infringe the Chapter I prohibition if it involves coordination between competitors with the aim of restricting competition. This could range from exchanging commercially sensitive information such as future pricing strategies or business plans to coordinating responses to a tender (bid rigging).

Communications may also be subject to review under the Chapter II prohibition where they serve to disparage a competing product.

viii. Public communications: To what extent may public communications constitute violation of antitrust laws?

Public communications (press releases, etc) may only represent a competition law concern when they facilitate coordination between competitors, e.g. via price-signalling. Price-signalling is rare in non-commoditised markets (such as the pharmaceutical sector), although may arise from transparency obligations

Unilateral conduct by a dominant company may be problematic where public statements are used to disparage competing products.

ix. Exchange of information: Are anticompetitive exchanges of information more likely to occur in the pharmaceutical sector given the increased transparency imposed by measures such as disclosure of relationships with HCPs, clinical trials, prices, etc?

The pharmaceutical sector is subject to numerous regulatory and ethical transparency measures, for example, regarding financial relationships with HCPs or other healthcare organisations, public price or reimbursement information and information about clinical trial registrations and results. Disclosures need to be carefully managed to avoid facilitating anti-competitive coordination. Companies should have clear internal controls over what information is disclosed and how that disclosure takes place. The competition law concern is the capacity for such disclosures to undermine independent decision-making, e.g. by allowing competitors to predict next steps regarding e.g. a product's pipeline development or launch, or otherwise monitor rivals' activity.

Trade associations may assist with such annual disclosure requirements, e.g. the ABPI code of practice includes guidelines to assist members.

The CMA has penalised information sharing in the pharmaceutical sector, e.g. *Nortriptyline* (sharing of competitively sensitive information to maintain prices).

5. Anticompetitive Unilateral Conduct

i. Abuse of dominance: In what circumstances is conduct considered to be anticompetitive if carried out by a firm with monopoly or market power?

Practices departing from competition on the merits may be considered abusive under the Chapter II prohibition when carried out by a dominant company.

In the pharmaceutical sector, the CMA (and its predecessor the OFT) have investigated numerous types of abuse:

- Excessive and unfair pricing (*Napp*, *Liothyronine*, *Phenytoin* and *Hydrocortisone*)
- Predatory pricing (*Napp*)
- Margin squeeze ([Genzyme](#))
- Tying and bundling (*Genzyme* – abuse not established on the facts of the case)
- Foreclosure abuses, including:
 - ‘Pay-for-delay’ (*Paroxetine*)
 - Withdrawing and delisting a product from the NHS prescription channel to hinder the development of generic competition ([Gaviscon](#))
- Misleading claims about competing products ([Vifor](#))
- Loyalty-inducing discounts or rebates ([Remicade](#) – no grounds for action decision rendered as the conduct had no effect; [Case CE/9855-14](#) – warning letter regarding competition concerns that may arise when dominant companies offer loyalty-inducing discounts and rebates).
- The European Commission has fined pharmaceutical companies for various other conduct hindering generic entry, which the CMA would be expected to follow, including:
- Misuse of the patent system ([Copaxone](#), currently under appeal; [AstraZeneca](#))
- Deregistration of marketing authorisations (*AstraZeneca*)
- ‘Killer’ acquisitions of a competing product or technology (e.g. *Servier*, currently under appeal).

The CMA has flexibility to investigate other types of conduct where it has the potential to affect competition on the relevant markets.

ii. De minimis thresholds: Is there any de minimis threshold for a conduct to be found abusive?

There is no de minimis threshold for the Chapter II prohibition (although conduct by non-dominant undertakings is not caught by the prohibition).

iii. Market definition: Do antitrust authorities approach market definition in the context of unilateral conduct in the same way as in mergers, if not, what are the main differences and what justifies them?

Generally, the approach to market definition is similar to that in mergers. However, merger control is forward looking, while in unilateral conduct cases the focus is generally past behaviour. A specific issue arises where generic entry is imminent (or has occurred). Once generic entrants have formed an

effective strategy for significant market entry, the market is likely to be defined at the level of the active ingredient (ATC5), see the CAT judgment in [Generics \(UK\) \(Paroxetine\)](#).

Also, the CMA must adopt a definitive market definition in order to establish dominance, meaning that the economic assessment can be more rigorous. Perhaps as a result, the CMA has on occasion adopted market definitions even narrower than the relevant molecule, see e.g., *Phenytoin*.

iv. Establishing dominance: When is a party likely to be considered dominant or jointly dominant? Can a patent owner be dominant simply on account of the patent that it owns?

The concept of dominance in UK law is similar to EU law, and involves: “A position of economic strength ... which enables [an undertaking] to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers” ([Case 85/76 Hoffmann-La Roche v Commission](#)).

Factors to consider when assessing market power include market share, competitors (existing/potential), barriers to entry and countervailing buyer power. The UK competition authorities have held that the NHS (as a “single buyer” of pharmaceutical products) does not exert countervailing buyer power vis-à-vis a dominant supplier (see e.g. *Gaviscon*, *Paroxetine*).

Holding a patent does not necessarily create a dominant position – this will depend on the extent to which substitutes for the product/process underlying the patent exist (see [OFT402](#)). However, the existence of a patent may constitute a barrier to entry: a patent holder can litigate and seek injunctions in response to planned market entry of a competitor (as the CMA found in *Paroxetine*).

v. IP rights: To what extent can an application for the grant or enforcement of a patent or any other IP right (SPC, etc) expose the patent owner to liability for an antitrust violation?

Exceptionally, certain practices regarding the application or enforcement of a patent may be abusive (note that many of these practices have not yet been considered by the CMA, so EU investigations and pre-Brexit case law are discussed below):

- Misuse of the patent system.
 - **Copaxone:** The Commission found that Teva misused the patent system by submitting staggered applications for divisional patents, and then strategically withdrawing them, creating prolonged legal uncertainty which delayed generic entry. Teva is appealing this finding.
 - **AstraZeneca:** The Commission fined AZ for misleading representations to patent offices and national courts that resulted in it acquiring unwarranted SPCs for omeprazole (Losec), thus delaying generic entry. the General Court held that “the enforcement of a patent can amount to an abuse of a dominant position only when the undertaking has wilfully acquired or enforced the patent knowing that it is invalid”.
- Creation of “patent thickets”. It may be abusive for a dominant firm to engage in excessive patenting, creating a “thicket” of patents that delays/increases the cost of entry for competitors. The EC [investigated Boehringer](#) for allegedly applying for unmeritorious patents to hinder a competitor from accessing the market with its own competing medicine (investigation closed following settlement between the parties).

vi. IP rights: When would life-cycle management strategies expose a patent owner to antitrust liability?

Patent holders should ensure that life-cycle management strategies do not fall outside competition on the merits.

In *Gaviscon*, the OFT (predecessor of the CMA) found that Reckitt Benckiser (RB) abused its dominant position by withdrawing NHS packs of 'Gaviscon Original' after patent expiry and replacing it with 'Gaviscon Advanced' (patent protected). In the circumstances, this prevented GPs from prescribing the generic of the original product and so delayed generic entry.

vii. Communications: Can communications or recommendations aimed at the public, HCPs or health authorities trigger antitrust liability?

The CMA has taken action regarding alleged disparagement. In *Vifor*, the CMA investigated whether the company had restricted competition by spreading misinformation to healthcare professionals about a rival product. The CMA accepted commitments from Vifor (including an ex gratia payment of £23 million to the NHS), stating: "*The dissemination of misleading claims by dominant undertakings to public authorities, HCPs, customers and other relevant stakeholders in the pharmaceutical context could fall outside of competition on the merits and, therefore, constitute an abuse of a dominant position*". The CMA emphasised that UK rules on advertising of medicines require suppliers to compete based on clear, accurate, verifiable and non-misleading information.

viii. Authorised generics: Can a patent owner market or license its drug as an authorised generic, or allow a third party to do so, before the expiry of the patent protection on the drug concerned, to gain a head start on the competition?

Yes, such practices are generally legitimate, although allowing a third party to launch an authorised generic instead of launching its own product could constitute or form part of a "pay-for-delay" arrangement.

ix. Restrictions on off-label use: Can actions taken by a patent owner to limit off-label use trigger antitrust liability?

There is as yet no UK case law directly addressing this issue. However, UK law is likely to follow the approach of the CJEU in *Hoffman-La Roche / Novartis* ([Case C-179/16](#)) where it confirmed that action by a dominant patent owner with the aim of limiting off-label use may constitute an abuse.

x. Pricing: When does pricing conduct raise antitrust risks? Can high prices be abusive?

Pharmaceutical pricing has historically been a particular area of focus for the CMA's enforcement of competition law. Excessively high and low prices can be abusive and certain rebates structures may also create competition law risk.

The CMA has imposed several fines for excessively high pricing in a range of cases including *Phenytoin*, *Liothyronine* and *Hydrocortisone*. UK law applies a two-stage approach to excessive pricing based on the test established in the CJEU's *United Brands* judgment. This considers whether prices are:

- significantly and persistently excessive compared to a competitive benchmark price (cost plus a reasonable margin), and (if so)
- unfair – either in themselves or when measured against relevant benchmarks.

In a recent non-pharmaceutical case, the CAT found that a price 20% above the competitive benchmark would be excessive for the purposes of the first limb of this test ([Le Patourel v BT](#)). However, these tests

are particularly complex to apply in relation to pharmaceutical products subject to patent protection and, to date, CMA enforcement activity has focused on generic medicines.

In *Napp*, the OFT (predecessor to the CMA) found Napp guilty of excessively low “predatory” pricing by charging hospitals prices below its average variable costs (for which it used direct costs as a proxy), as well as finding that Napp charged excessive and unfair prices when patients were discharged into the community.

In *Remicade*, the CMA investigated whether a “loyalty inducing” discount scheme could constitute an abuse. Under the scheme, the hospitals would lose the benefit of the discount if they switched even a small portion of their demand to biosimilar alternatives to Remicade. Ultimately, the CMA found that, although the discount structure was designed to limit or delay biosimilar entry, on the specific facts it was not likely to restrict competition. It therefore closed its investigation on a “no grounds for action” basis.

xi. Sector-specific issues: To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise infringe antitrust rules?

To date, no specific features of the pharmaceutical sector have been identified that would provide an objective justification for conduct that otherwise amounts to a competition law infringement. However, the CMA will consider the specific legal and economic context of conduct it is investigating on a case-by-case basis.

6. Updates and Trends

i. Recent developments: Are there in your jurisdiction any emerging trends or hot topics regarding antitrust regulation and enforcement in the pharmaceutical sector?

Following political pressure, the CMA has recently sought to move towards a faster, more transparent and more proportionate enforcement of competition law. Its [2026/2027 Annual Plan](#) refers to the “4Ps” – pace, predictability, proportionality and process. In the pharmaceutical sector this may signal quicker intervention in core problematic practices such as delaying generic market entry or excessive pricing and, potentially, provision of further guidance to assist companies with legal compliance. Economic growth is a current CMA priority and (in a merger context) this may lead to remedies more specifically targeted at supporting innovation and investment.

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