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PHARMACEUTICAL ANTITRUST

European Union

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Pharmaceutical Antitrust

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Contents

Pharmaceutical Antitrust

UPDATES AND TRENDS

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European Union

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PHARMACEUTICAL REGULATORY LAW

Regulatory framework

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

European legislation requires that a medicinal product first obtains a marketing authorisation (MA) before it can be placed on the EU market. The key pieces of EU legislation governing the authorisation and marketing of pharmaceutical products are Directive 2001/83/EC on the Community code relating to medicinal products for human use and Regulation 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products and establishing a European Medicines Agency. This legislation does not, however, cover pricing aspects, which are left to national authorities for their respective jurisdictions.

MAs can be obtained through various procedures: mutual recognition procedure, decentralised procedure, centralised procedure or national procedures. For some categories of medicinal products, such as biological products or drugs intended to treat serious diseases, the centralised procedure is mandatory. Within each type of procedure, there are also different routes MA applicants can choose, based on the type of product being applied for: a generic/biosimilar route for generic or biosimilar versions of previously authorised medicines, a 'full dossier' route for a new medicine and a 'hybrid' route for medicines that are a mix of the two categories. Abridged and accelerated procedures are also available, for example, in the case of medicines that address an unmet medical need in the community. For example, the 'conditional marketing authorisation' procedure can be used to expedite the approval of safe and effective medicines in the interest of public health. This route was used for the authorisation of covid-19 vaccines.

The European Commission (Commission) is currently reviewing the EU's general pharmaceutical legislation. On 26 April 2023, the Commission adopted a proposal for a new Pharmaceuticals Directive and a new Pharmaceuticals Regulation, which will revise and replace the existing general pharmaceutical legislation (Regulation 726/2004 and Directive 2001/83/EC mentioned above) and the legislation on medicines for children and for rare diseases (Regulation 1901/2006 and Regulation 141/2000/EC, respectively) are also currently under review. The proposals have been considered by the European Parliament and are currently with the Council for review. The Commission has not provided an estimated time frame for adoption. Following adoption, there will also be an 18-month transitional period to allow for change over to the new regulations.

Law stated - 20 May 2025

Regulatory authorities

Which authorities are entrusted with enforcing these rules?

The main authorities responsible for the authorisation of medicinal products are the Commission and the European Medicines Agency (EMA) (at the EU level) and the national regulatory authorities (at the national level). These authorities are also responsible for the

ongoing monitoring of the marketing of the medicinal product within their jurisdictions once it has been authorised.

Law stated - 20 May 2025

Pricing

Are drug prices subject to regulatory control?

Drug prices are generally subject to some level of regulatory control, but this is subject to the sole jurisdiction of individual member states. There is no harmonised regulation covering pricing of drugs in Europe.

Law stated - 20 May 2025

Distribution

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

The distribution of pharmaceutical products is largely governed by national legislation within each member state, although there is some overarching EU legislation (such as the rules relating to supply set out in Directive 2001/83/EC) aimed at ensuring that the medical needs of the patients in the EU are adequately met. In addition, the Commission and the European courts are tasked with general oversight of the market and ensuring that all laws and regulations promote access to healthcare and medicines and protect public health.

At a national level, a number of factors determine the applicable rules and distribution channels for a product. The category and type of product play a major role (eg, hospital only, pharmacy only, doctor-administered therapy, etc). There are also different rules governing the channels of supply themselves (eg, different member states take different approaches to dispensing of medicines online).

Law stated - 20 May 2025

Intersection with competition law

Which aspects of the regulatory framework are most directly relevant to the application of competition law to the pharmaceutical sector?

The existence of strong regulatory constraints does not prevent the application of competition law in the pharmaceutical industry, which is no different than any other sector. However, as recalled by the Court of Justice of the EU (CJEU), due account must be taken of these regulatory constraints (Case C-307/18, ***Generics (UK) and others***), which may therefore have an impact on the competition law analysis.

For example, the regulation of drug prices by health authorities does not prevent the intervention of competition authorities. On 10 February 2021, the Commission adopted its first decision on excessive pricing in the pharmaceutical sector, accepting commitments

from Aspen Pharmacare to reduce its prices for six critical cancer drugs by, on average, approximately 73 per cent, and ensuring a continued supply (Case AT.40394, ***Aspen***).

In addition, even though a particular course of action may be permitted under the regulatory framework (for example, withdrawal of a registration, it does not mean that it cannot be an infringement under competition law (see, eg, Case C-457/10 P, ***AstraZeneca***).

Law stated - 20 May 2025

COMPETITION LEGISLATION AND REGULATION

Legislation and enforcement authorities

What are the main competition law provisions and which authorities are responsible for enforcing them?

The main EU competition law provisions are set out in the Treaty on the Functioning of the European Union (TFEU): article 101, which prohibits anticompetitive agreements and practices; and article 102, which prohibits the abuse of a dominant position. These provisions are enforced by the Commission and National Competition Authorities across member states. Within the Commission, the Directorate-General for Competition (DG COMP) holds the primary responsibility for direct enforcement.

Regulation 139/2004 (EU Merger Regulation) gives the Commission the jurisdiction to review mergers and acquisitions if they meet the applicable thresholds (or, in certain circumstances, are referred to the Commission by member states or parties to the transaction).

Law stated - 20 May 2025

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?

The actions the Commission can take in relation to infringements of article 101 and article 102 TFEU are set out in Regulation 1/2003:

- Imposing fines up to 10 per cent of the company's worldwide turnover during the previous financial year.
- Requiring infringing companies to put an end to their behaviour and imposing behavioural or structural remedies that are proportionate to the infringement and necessary to bring the infringement effectively to an end.
- Ordering interim measures in cases of urgency where there is a risk of serious and irreparable damage to competition.
- Accepting legally binding commitments by companies to deal with anticompetitive concerns.
- Imposing daily penalties of up to 5 per cent of the average daily turnover in that year to ensure compliance with these measures.

Member state competition authorities generally have similar enforcement powers.

The Commission is currently evaluating whether to reform Regulation 1/2003 (see here).

The Commission's approach to remedies (commitments) in an antitrust investigation of a pharmaceutical case is illustrated by Case AT.40394 ***Aspen***. In May 2017, the Commission commenced a formal investigation into Aspen's pricing practices for six critical off-patent cancer medicines. Aspen had acquired the medicines from another company and started to increase prices from 2012, often by several hundred per cent. Its prices exceeded relevant costs by almost 300 per cent on average. Aspen gave commitments to the Commission (made legally binding in February 2021), under which it agreed to reduce its prices by 73 per cent on average and to ensure continued supply of the medicines for a significant period. On this basis, the Commission closed its investigation without sanctioning Aspen.

Likewise, in July 2024, the Commission accepted commitments from Vifor Pharma and on that basis closed its investigation without a finding of infringement or sanction (Case AT.40577). The Commission reached a preliminary view that Vifor had abused a dominant position in national markets for intravenous iron treatment by carrying out a campaign of disparagement (by disseminating potentially misleading information) against its closest competitor in Europe. Vifor committed to (1) launch a comprehensive multi-channel communication campaign to correct and undo the effects of the previous potentially misleading messages, (2) refrain from making any external promotional or medical communication, written or oral, about the safety profile of the competitor for a period of 10 years throughout the European Economic Area and (3) implement a number of measures and safeguards to ensure compliance, including internal mechanisms to ensure that all relevant external promotional and medical communications, as well as internal training materials, comply with the commitments prior to their use, as well as annual internal training of staff and a system of certification of compliance.

It remains relatively rare for the Commission to accept commitments to close an investigation. In another recent antitrust decision relating to disparagement (among other things) the Commission fined Teva €462.6 million (Case AT.40588, ***Teva/Copaxone***).

Law stated - 20 May 2025

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?

Anyone who has suffered harm as a result of a breach of EU competition law is entitled to seek damages as provided for under the EU Damages Directive and preceding case law (cases C-453/99, ***Courage*** and C-295/04 to C-298/04, ***Manfredi***).

These private enforcement actions must be brought before the national courts in member states and are primarily governed by the national law of those member states. The remedies available will thus depend on national law and procedure and may include, for example, damages or injunctions. The national courts can refer legal questions to the European Court of Justice.

There are two avenues for a private party to bring a damages action for an infringement of EU Competition Law before a national court. It could do so without relying on a prior Commission decision (referred to as a 'standalone' action). Alternatively, it could do so in reliance on a previous infringement decision by a competent competition authority at the EU or member state level (referred to as a 'follow-on' action).

Law stated - 20 May 2025

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?

Article 17 of Regulation 1/2003 gives the Commission the power to conduct general inquiries into any sector. The German government has publicly expressed its support for empowering the European Commission to impose remedies, which may encourage further reforms of the Commission's powers in the future.

In 2008, the Commission carried out an inquiry in the pharmaceutical sector, based on the view that competition in the sector was failing to function optimally in terms of pricing and innovation. The Commission published its final report in July 2009. Its findings included that generic medicines were taking too long to reach the market; few innovative medicines were reaching the market; and there was a need to implement an EU patent and patent-litigation system. The report has been highly influential on its subsequent enforcement activities.

The Commission issued another report in January 2019 setting out the enforcement action taken in relation to antitrust in the pharmaceutical sector between 2009 and 2017. This highlighted the need for competition authorities to continue their commitment to enforce competition law in the sector. Following the report, the Commission adopted a 'Pharmaceutical strategy for Europe' in November 2020. This is primarily focused on:

- ensuring accessibility and affordability of medicines;
- supporting innovation and competition in the European pharmaceutical sector;
- improving crisis preparedness and response mechanisms; and
- continuing international dialogue to promote a high level of quality, efficacy and safety standards.

On 26 January 2024, the Commission published a further report summarising recent competition enforcement in the pharmaceutical sector for 2018–2022. This covers the activities of the Commission and also national competition authorities (NCAs). This highlights, among other things, that the Commission or NCAs adopted 26 decisions fining companies more than €780 million over the period or accepting commitments and investigated more than 70 other cases (40 of which were ultimately closed and 30 of which were ongoing as at January 2024). The Commission also reviewed more than 30 mergers, identifying concerns and requiring remedies in five cases.

Law stated - 20 May 2025

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?

Health authorities and regulatory bodies do not enforce competition law, which is the exclusive jurisdiction of the competition authorities and courts at the EU level and in member states.

Nevertheless, competition authorities may consult health authorities or regulators in the course of their investigations (and, if necessary, can require them to provide information) to get a better picture of the potential anticompetitive effects of an agreement or practice. Likewise, competition authorities may consult them in the context of sector inquiries.

Law stated - 20 May 2025

NGO involvement

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

Although not directly involved in the application of competition law, NGOs, trade associations and consumer groups may have a role to play in the context of the Commission's competition law investigations or market inquiries. For example, they may highlight instances where markets are not working well or make a complaint about anticompetitive agreements or conduct.

They may also intervene in a case before the European courts if they can pass the procedural hurdle of establishing sufficient interest in the case.

Law stated - 20 May 2025

REVIEW OF MERGERS

Thresholds and triggers

What are the relevant thresholds for the review of mergers in the pharmaceutical sector?

The standard EU merger control regime, as set out in the EU Merger Regulation (EUMR) and related legislation and guidance, applies to all markets, with no special rules or thresholds for the pharmaceutical sector.

A transaction is subject to the EUMR and therefore notifiable to the EU Commission where it: (1) constitutes a 'concentration'; and (2) has an 'EU dimension'. If a transaction does not constitute a concentration or does not have an EU dimension, parties will need to consider whether it falls within the scope of member states' national merger control rules.

A concentration requires a 'change of control on a lasting basis'. Control for these purposes is defined as the ability to exercise 'decisive influence' over an undertaking on the basis of rights,

contracts or other means. This can include 'joint control' where two or more parties exercise decisive influence over an undertaking (additional rules apply to joint ventures, notably that they are formed on a lasting basis and are 'full function').

There are two alternative tests to establish whether a concentration has an EU dimension.

- The combined worldwide group turnover of all undertakings concerned exceeds €5,000 million and the EU-wide group turnover of each of at least two of the undertakings concerned exceeds €250 million, unless each undertaking concerned achieves more than two-thirds of its EU-wide turnover in one and the same member state.
- The combined worldwide group turnover of all undertakings concerned exceeds €2,500 million; in each of at least three member states, the combined group turnover of all undertakings concerned exceeds €100 million; and in each of at least three of those member states, the group turnover of each of at least two of the undertakings concerned exceeds €25 million, unless each undertaking concerned achieves more than two-thirds of its EU-wide turnover in one and the same member state.

There are also two referral mechanisms by which the Commission can review mergers even if the above thresholds are not met.

- First, under article 4(5) EUMR, if a concentration is notifiable in at least three member states, the parties may request the Commission to review the concentration.
- Second, under article 22 EUMR, a member state may request the Commission to review a concentration where the concentration poses a threat to competition in the territory of the referring state.

In relation to article 22, the Court of Justice of the EU (CJEU) in September 2024 held that the Commission cannot accept an article 22 referral where the transactions fell below the jurisdictional thresholds of the referring member state (Joined Cases C-611/22 P and C-625/22 P ***Illumina/GRAIL***). In light of this judgment the Commission withdrew the 2021 guidance in which it had encouraged such referrals where the merger may limit competition.

The Commission had instituted the policy to catch 'killer acquisitions', which would not be caught by many turnover-based thresholds because, for example, the target company is a start-up with insufficient turnover or market share. This is directly relevant to the pharmaceutical sector with regard to such companies that are engaged in clinical studies to introduce products or biotech startups (the Commission specifically identifies the pharmaceutical sector as a good candidate for such referrals in its withdrawn guidance).

Following the judgment, the Commission has been considering alternative routes to reviewing mergers falling below turnover thresholds. Some member states may be able to make references based on market share tests or size of transaction tests. An increasing number of others have the power to 'call in' transactions falling below their thresholds but which may affect competition. The Commission accepted an article 22 referral of a case 'called in' by Italy in case M.11766 ***Nvidia/Run:ai***. In January 2025, Nvidia appealed this to the EU General Court (case T-15/25). The Commission is also considering amendments to the thresholds in the EU Merger Regulation, but there is no consensus for this.

Another route by which mergers falling below the merger control thresholds can still be reviewed is under the CJEU's *Towercast* judgment (C-449/21). On 16 March 2023, the Court

held that a transaction that is not notifiable under the EUMR (ie, a concentration with no EU dimension) or under national merger control rules, and that is not subject to a referral to the Commission under article 22 of the EUMR, may still be reviewed by a national competition authority under article 102 of the TFEU, provided that the acquirer, which holds a dominant position on a given market, substantially impeded competition on that market through the acquisition under review. While not a pharmaceutical sector case, it provides a basis for national competition authorities to review transactions by a dominant company (as pharma patent-holders may be at points in the product life cycle) of companies or assets with little or no revenue (as may be the case for products not yet on the market), as an alternative to seeking review by the Commission under article 22). Indeed, in her opinion, Advocate General Kokott stated:

> supplementary application of article 102 TFEU, similar to that of article 22 of the Merger Regulation, is likely to contribute to the effective protection of competition in the internal market, in so far as concentrations which are problematic under competition law do not meet the thresholds under merger control law and are therefore not subject, in principle, to ex ante control. This is because, as the Italian Government and the Commission point out, a gap in protection has emerged in recent years in the coverage and control, under competition law, of acquisitions of innovative start-ups, for example in the fields of internet services, pharmaceuticals or medical technology ('killer acquisitions'). This concerns situations in which established and powerful undertakings acquire emerging undertakings which do not yet have a large turnover and which operate in the same, neighbouring, upstream or downstream markets, at an early stage of their development in order to eliminate them as competitors and consolidate their own market position. In order to ensure effective protection of competition in that respect also, it should therefore be possible for a national competition authority to resort at least to the 'weaker' instrument of punitive ex post control under Article 102 TFEU, provided that the conditions for it are met.

Merging parties and their advisers should also be aware of the Commission's package to further simplify its procedures for reviewing concentrations under the EUMR, which applied from 1 September 2023. This includes: (1) a revised Merger Implementing Regulation- , (2) a Notice on Simplified Procedure and (3) a Communication on the transmission of documents. The main changes to the previous rules expand and clarify which cases can be treated under the simplified procedure; streamline the review of simplified cases and non-simplified cases, including new notification forms; and optimise the transmission of documents to the Commission.

In addition, the EU's Foreign Subsidies Regulation (2022/2560) (FSR) entered into force on 12 July 2023, introducing a new regime, separate from the merger control review process, which requires parties to a transaction to submit a notification to the Commission and suspend implementation pending clearance by the Commission in circumstances when they have received financial support from non-EU governments (ie, foreign financial contributions (FFCs)). A transaction is subject to the FSR and therefore notifiable to the EU Commission if: (1) it constitutes a 'concentration'; (2) it has an 'EU dimension' (which is a different threshold from the EUMR, namely that the target, one of the merging parties or the joint venture has an EU turnover of €500 and is established in the EU); and that (3) all parties together have

received at least €50 million in FFCs from non-EU countries in the three years preceding the notification. Given the wide notion of FFCs, pharmaceutical companies can easily meet the relevant threshold for FFCs through the sale of pharmaceutical products to states and state entities (eg, NHS payers and public hospitals).

While foreign direct investment (FDI) reviews take place at the national rather than EU level, the Commission's guidelines for EU member states on implementing national FDI regimes expressly recommend including healthcare and pharmaceuticals within scope. These are areas where member states often have mandatory notification obligations, which usually means that completion is prohibited pending clearance.

Law stated - 20 May 2025

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?

An acquisition of control over assets (including patents or licences) may be a concentration and therefore potentially notifiable under the EUMR only if they constitute the whole or part of an undertaking, namely, a business with a market presence to which turnover can be clearly attributed either presently or in the foreseeable future (see Commission's Consolidated Jurisdictional Notice paragraph 24 and Case M.7872 *Novartis/GSK ofatumumab autoimmune indications*).

Law stated - 20 May 2025

Market definition

How are the product and geographic markets typically defined in the pharmaceutical sector?

Product market

In defining the relevant product and geographic market the Commission needs to consider which products are substitutable and hence which products exert competitive constraint. The Commission follows the guidance in its Market Definition Notice, which was revised in February 2024. The updated notice adapts the existing principles, methodologies, case law and best practices to the modern context of antitrust and merger cases.

It contains the following key elements: improved accessibility through a structured format and practical examples; identification of general principles for market definition; recognition of the importance of non-price factors such as innovation, quality, security of supply and sustainability; and tailored guidance for specific circumstances such as digital markets and innovation-driven industries. In addition, industries with significant research and development (R&D) activities, such as pharmaceuticals, chemicals, electrical equipment and hardware technology, are subject to specific considerations.

While the characteristics of the pharmaceutical industry are usually taken into account in the competition assessment, they may also influence market definition. For 'pipeline' products,

where products are in development but not yet available, the Commission assesses potential substitutability with existing products to determine market coverage. However, for early-stage R&D projects, the definition of a relevant product market may still be difficult. Nevertheless, the Commission may draw competitive boundaries based on factors such as the nature of the innovation effort, the research objectives and the specialisation of the team.

For pharmaceutical products, the Commission typically takes into account EPMRA's ATC3 level classification as its starting point, on the basis that all products in the same ATC3 class generally have the same therapeutic indication and cannot be substituted by products from other ATC3 classes. However, the Commission will consider the characteristics of the products in question and may depart from the ATC3 level, including in particular looking at the narrower ATC4, or by molecule (the latter in particular for cases involving generics). For OTC products, the Commission follows a similar approach and may use IQVIA's CHC classification (including also natural remedies as appropriate) (M.9274- , *GlaxoSmithKline/Pfizer Consumer Healthcare Business*).

The Commission tends to segment the market between prescription and OTC products; however, in some cases has considered competition between them (M.9274 *GlaxoSmithKline/Pfizer Consumer Healthcare Business*).

It may also consider segmentation between other factors relevant to the product in question, such as the line of treatment, mode of action, route of administration, etc (M.9294 *BMS/Celgene*).

For active pharmaceutical ingredients (APIs), the Commission's general approach is that each API belongs to a separate product market. However, it will also consider substitutability between APIs, either in general or for certain applications (M.7746 *Teva/Allergan Generics*).

Geographic market

The Commission has consistently considered that the markets for finished-dose pharmaceutical products are national in scope, in particular in view of the national regulatory and reimbursement schemes and the fact that competition between pharmaceutical firms still predominantly takes place at a national level. For pipeline products and APIs, the Commission has considered the geographic scope of the market to be at least EEA-wide (M.9461 *AbbVie/Allergan*, M.7746 *Teva/Allergan Generics*).

Law stated - 20 May 2025

Sector-specific considerations

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

The Commission's guidelines on horizontal mergers and non-horizontal mergers are sector-agnostic. However, the Commission is increasingly considering potential and innovation competition in pharmaceutical markets. It refers to its competitive assessment framework as having four-layers, corresponding to overlaps between the parties' activities in terms of:

- Actual (product and price) competition, assessing the overlaps between the parties' existing (marketed) products.
- Potential (product and price) competition, assessing the overlaps between the parties' existing (marketed) and pipeline products at advanced stages of development and between the parties' pipeline products at advanced stages of development. For pharmaceutical products, the Commission in principle considers programmes in Phase II and III clinical trials as being at an advanced stage of development.
- Innovation competition in relation to the parties' ongoing pipeline products, assessing the risk of significant loss of innovation competition resulting from the discontinuation, delay or redirection of the overlapping pipelines (including early stage pipelines).
- Innovation competition in relation to the capability to innovate in certain innovation spaces, assessing the risk of a significant loss of innovation competition resulting from a structural reduction of the overall level of innovation (M.9294 ***BMS/Celgene***).

In May 2025, the Commission launched a review of both its horizontal and non-horizontal merger guidelines. Its review, which will lead to revised guidelines, is focusing on how the Commission's assessment of mergers should give adequate weight to areas including innovation, efficiency, resilience, investments, intensity of competition in certain strategic sectors, sustainability and other transformational needs of the European economy.

Law stated - 20 May 2025

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?

Parties can put forward efficiency arguments (such as the strengthening of R&D), as a factor counteracting harmful effects on competition that might otherwise result from a merger.

To take efficiencies into account, the Commission must be able to conclude that the efficiencies benefit consumers, are merger-specific and are verifiable (see the Commission's Horizontal Merger Guidelines). In practice, this is a difficult burden of proof for the Commission to satisfy; however, the Commission's approach to efficiencies is one of the areas of focus in its review of the merger guidelines launched in May 2025. The local or regional nature of R&D is unlikely to be a relevant factor taken into account.

Law stated - 20 May 2025

Horizontal mergers

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

The Commission must assess whether or not a merger would significantly impede effective competition, in particular as a result of the creation or strengthening of a dominant position, in the common market or a substantial part of it (see the Commission's Horizontal Merger Guidelines and the Court of Justice of the EU's July 2023 judgment in C-376/20 P *Commission v CK Telecoms UK Investments*).

In relation to mergers in the pharmaceutical sectors, the Commission will look at overlaps between marketed products, pipeline products and also between capabilities to innovate (M.9294 ***BMS/Celgene***).

Many mergers in the pharmaceutical sector have led to a large number of horizontal affected markets and the Commission's approach has been to apply a system of filters to identify the markets on which to focus its analysis (M.11383***Cooper/Viatris***). Group 1 are markets where the parties' combined market share exceeds 35 per cent and the increment exceeds 1 per cent. Group 1+ are markets where the parties' combined market share is less than 35 per cent but only one competitor remains in the market; or where the parties' combined share exceeds 35 per cent and the increment is less than 1 per cent but the party with the smaller increment is a recent entrant. Group 2 are where the parties' combined market share exceeds 35 per cent but the increment is below 1 per cent. Group 3 are where the parties' combined market share is between 20 per cent and 35 per cent. The Commission will assess whether there are competition concerns in each of these groups, but will focus its investigation primarily on the first group.

Law stated - 20 May 2025

Product overlap

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

For pharmaceutical products, the Commission in principle considers potential competition between pipeline and marketed products and between pipeline products. The Commission will look carefully at pipeline product overlaps, in particular products in Phase II and III clinical trials (which are seen as an advanced stage of development) but also products at earlier development stages. Overlaps between these and other pipeline products or marketed products may be a concern if the merger is likely to lead to the discontinuation or reorientation of R&D efforts thus preventing a potentially competing product entering the market.

In addition to pipeline products, the Commission will also look at innovation competition in relation to the capability to innovate in certain innovation spaces, assessing the risk of a significant loss of innovation competition resulting from a structural reduction of the overall level of innovation rather than in relation to specific product or pipeline product overlaps (M.9294 ***BMS/Celgene***).

Examples of cases where the Commission has found competition concerns relating to pipeline products include ***Novartis/GlaxoSmithKline Oncology*** (M.7275), in which it was concerned that Novartis would post-transaction cease development of a pipeline cancer product; ***Pfizer/Hospira*** (M.7559) in which it raised concerns relating to Pfizer's incentives to continue development of its own biosimilar once it owned Hospira's biosimilar; ***AbbVie/Allergan*** (M.9461) in which the Commission considered that AbbVie

would post-transaction likely cease development of Allergan's R&D for a competing product; and ***Takeda/Shire*** (M.8955) in which it found that Takeda would be unlikely to continue developing Shire's new anti-integrin treatment, which would compete closely with Takeda's biologic treatment for inflammatory bowel disease.

Law stated - 20 May 2025

Remedies

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

The Commission's framework for remedies in mergers in the pharmaceutical sector is well established and the Commission has cleared a number of cases conditional on remedies.

Generally, and in particular to secure Phase I clearance, the parties must commit to divest the acquirer or target's business in the market in which the Commission has competition concerns. The divestment may be structured as an asset carve-out or sale of a business, but would need to be a viable business and thus include the applicable marketing authorisations, contracts and brands, customer lists, key personnel, as well as transitional manufacturing and supply arrangements, etc.

For example, in ***Mylan/Upjohn*** (M.9517), the Commission identified concerns in some markets due to the strong position of the merging parties and the limited number of significant competitors. The parties resolved these concerns by committing to divest Mylan's business in the relevant markets to a suitable purchaser.

The Commission adopted a similar approach recently (June 2024) in ***Cooper/Viatris*** (M.11383). It identified concerns in two national markets for over the counter pharmaceuticals. In particular, it found that the transaction would have led to high combined market shares as well as high concentration levels. It also found that post-merger there would not be sufficient potential competitors to exert competitive pressure on the merged entity. Cooper resolved these concerns by committing to divest Cooper's relevant business in the relevant markets (Portugal and Germany) to a suitable purchaser. It also committed to divest, at the option of the purchaser, the corresponding businesses in France and Ireland (where the Commission had not identified competition concerns), to increases the viability of the divestment businesses.

An example of a remedy in relation to pipeline products is ***AbbVie/Allergan*** (M.9461). The Commission found that a product Allergan was developing was likely to compete closely with a product AbbVie was developing and post-transaction AbbVie would potentially discontinue developing Allergan's product. The Commission was concerned that the merger would lead to a loss of innovation for the relevant treatments, as the products are a promising class of biologics for which only two other competing pipeline products existed. As a remedy, AbbVie committed to divest Allergan's pipeline product, including the development, manufacturing and marketing rights at a worldwide level, to a purchaser that would continue development of the product.

Law stated - 20 May 2025

ANTICOMPETITIVE AGREEMENTS

Assessment framework

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

Restrictive agreements and practices are regulated under article 101 of the Treaty on the Functioning of the European Union (TFEU).

Article 101(1) TFEU prohibits agreements, decisions by associations of undertakings and concerted practices that may affect trade between member states and have as their object or effect the prevention, restriction or distortion of competition within the internal market. A number of examples are listed under article 101(1) TFEU (eg, price fixing, bid rigging, market sharing) but this list is not exhaustive.

Article 101(2) TFEU provides that any such agreements will be automatically void and unenforceable.

Article 101(3) provides for the possibility of an exemption if certain criteria are satisfied; essentially that the pro-competitive benefits of the arrangement outweigh their anticompetitive effects.

On 1 June 2024, the Commission adopted updated rules to replace the horizontal guidelines and regulations adopted in 2010. The revised guidelines include: two new horizontal block exemption regulations (HBERs) on the application of article 101(3) of the TFEU to certain types of research and development agreements (R&D Regulation) and specialisation agreements (Specialisation Regulation).

These HBERs exempt certain R&D and specialisation agreements that would otherwise be caught by article 101(1) of the TFEU on the basis that they fulfil the conditions of article 101(3) of the TFEU.

The Commission has also published updated Guidelines on the application of article 101 to horizontal cooperation agreements, which provide detailed guidance on the interpretation and application of the HBERs. They also provide more general guidance on the assessment under article 101(1) and (3) of various types of horizontal cooperation agreements, including R&D and specialisation agreements, as well as purchasing, commercialisation, standardisation, standard terms and information exchange agreements.

Law stated - 20 May 2025

Technology licensing agreements

To what extent are technology licensing agreements considered anticompetitive?

The Commission has published specific guidelines on the application of article 101 TFEU to technology transfer agreements (2014/C 89/03). These note that most licensing agreements do not restrict competition and create pro-competitive efficiencies, as licensing leads to the dissemination of technology and promotes innovation by the licensor and licensees. To the extent that licence agreements do restrict competition, they also often give

rise to pro-competitive efficiencies and may benefit from the exemption under article 101(3) TFEU.

There is also a Technology Transfer Block Exemption Regulation (TTBER) (Regulation 316/2014), which applies to patent and know-how licence agreements and provides a 'safe harbour' where certain conditions are met. In particular, these include that the combined market share of the parties must not exceed 20 per cent if the parties are competing undertakings (horizontal agreements) and 30 per cent if the parties are not competing undertakings (vertical agreements); and the agreement must not contain any 'hardcore' restrictions, such as a restriction on the licensee's ability to determine its prices or the limitation of output, the allocation of markets or customers, restrictions on the use of the licensee's own technology.

The Commission is currently conducting a review of the TTBER and the related guidelines. In November 2024, it published a Staff Working Document summarising the results of its evaluation. It aims to publish and consult on draft revised texts in Q3 2025, and to adopt final revised texts in April 2026.

Law stated - 20 May 2025

Co-promotion and co-marketing agreements

To what extent are co-promotion and co-marketing agreements considered anticompetitive?

Co-promotion and co-marketing agreements are commonly used in the pharmaceutical sector.

- under a co-promotion agreement the same drug, under the same trademark, is promoted by two separate pharmaceutical companies; and
- under a co-marketing agreement, the companies promote and sell the same drug under different trademarks.

On the whole, the Commission has not raised objections of principle to these types of agreements, which it generally considers to be pro-competitive. However, companies need to take care not to use co-promotion or co-marketing agreements in a way that results in anticompetitive conduct.

For example, in 2013, the Commission fined Johnson & Johnson (J&J) and Novartis €16 million in relation to a co-promotion agreement for J&J's drug fentanyl. Novartis' subsidiary Sandoz had been on the verge of entering the market in the Netherlands with a generic version of fentanyl after J&J's patents had expired; however, Sandoz and J&J entered into a co-promotion agreement under which Sandoz did not launch its generic and received monthly payments under the co-promotion agreement. These were calculated to exceed the profits it would have made from selling its own product. The Commission found an infringement of competition law on the basis that the co-promotion agreement was not about marketing, but was about delaying generic entry and sharing the monopoly profits from the artificially higher prices that resulted.

Law stated - 20 May 2025

Other agreements

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

A key focus for the Commission in the pharma sector has been on agreements that hinder or delay the entry of generic medicines and the resulting price competition. The Commission has paid particular attention to 'pay-for-delay' agreements, which may take different forms but are generally entered into between a patent-holder and a generic company to delay generic entry after expiry of the patent-holder's core patents, in return for which the generic receives a value transfer from the patent-holder (eg, a lump sum payment or benefit under a co-promotion agreement, etc). See, for example, Cases AT.39226 ***Lundbeck***, AT.39612 ***Servier*** and AT.39686 ***Teva/Cephalon*** and subsequent appeals.

While the Commission has focused on 'pay for delay' agreements, companies need to pay attention that any agreements with competitors, whether in the context of research and development, joint production, joint marketing etc do not infringe competition law – this could, for example, include cartel type infringements, such as price-fixing, market-sharing and bid-rigging. The exchange of competitively sensitive information between competitors can be an infringement of itself; but including confidentiality provisions in an agreement would not resolve competition concerns where the agreement otherwise restricts competition.

In October 2023, the Commission imposed its first cartel sanction in the pharmaceutical sector (Case AT.40636). This related to an active pharmaceutical ingredient SNBB (an important input for the production of antispasmodic drugs). The Commission found a number of producers of SNBB had coordinated and agreed to fix the minimum sales price of the API to customers (price fixing) and to allocate quotas (market sharing). The companies also exchanged commercially sensitive information. Six of the companies involved (Alkaloids of Australia, Alkaloids Corporation, Boehringer, Linnea, Transo-Pharm and C2 PHARMA) admitted their involvement and agreed to settle the case, with fines totalling €13.4 million. The Commission's investigation into Alchem, which did not settle, continues and in June 2024 the Commission issued a Statement of Objections setting out its preliminary view that Alchem had engaged in the anticompetitive behaviour.

Nevertheless, cooperation between pharmaceutical companies is often pro-competitive. Recognising this, there are 'safe harbours' for certain R&D and specialisation agreements under block exemption regulations and the Commission has published guidelines on horizontal cooperation agreements. The Commission has recently revised many of these regulations and guidelines.

Law stated - 20 May 2025

Issues with vertical agreements

Which aspects of vertical agreements are most likely to raise antitrust concerns?

Vertical agreements (agreements between parties who operate at a different level of the supply chain), are generally considered less likely to raise competition law issues than

horizontal agreements (agreements between competitors). In principle, this is due to the complementary nature of the activities carried out by the parties to a vertical agreement and that vertical restraints may provide scope for efficiencies, for example, by optimising manufacturing and distribution processes and services. Nevertheless, the Commission recognises that undertakings with market power may, in certain cases, use vertical restraints to pursue anticompetitive purposes that ultimately harm consumers; vertical restraints can notably lead to foreclosure, softening of competition or collusion.

Vertical agreements that meet the conditions of the EU Vertical Agreements Block Exemption Regulation (VBER, the new version of which entered into force on 1 June 2022), benefit from an automatic exemption under article 101(3) TFEU.

In its Guidelines on Vertical Restraints (published in June 2022) the Commission sets out its framework for its assessment of vertical agreements. This includes those falling within the scope of the VBER and also those falling outside it – such agreements do not necessarily infringe competition law.

Aspects of vertical agreements most likely to raise antitrust concerns are those referred to in the guidelines as 'hardcore restrictions' and an agreement containing such restrictions cannot benefit from the VBER. These include restrictions on the price at which the products are to be sold by the distributor (resale price maintenance (RPM) and restrictions on the customers to whom, or the territories into which, a distributor is permitted to sell the products).

Other restrictions that must be assessed carefully for competition law compliance include single branding clauses (under which a buyer is obliged or induced to concentrate its orders for a particular type of product with one supplier (eg, in non-compete and quantity forcing clauses)), exclusive supply clauses, restrictions on the use of online marketplaces and the use of price comparison services, parity obligations, upfront access payments, category management agreements and tying.

An example of a competition law infringement in a vertical agreement in the pharmaceutical sector is ***GlaxoSmithKline*** (Joined cases C-501/06, C-213/06, C-515/06 and C-519/06). GSK had restricted its Spanish wholesalers from exporting its medicines to other member states, by agreeing with them that it would charge a higher price for sales for exports than for sales for the Spanish market. The Court of Justice of the EU held that an agreement aimed at limiting parallel trade should be considered as restrictive of competition 'by its object'. It also held that the Commission should have assessed a possible exemption under article 101(3), taking into account the arguments put forward by GSK in relation to the specific nature of competition in the pharmaceutical sector.

Law stated - 20 May 2025

Patent dispute settlements

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

Following its 2009 pharmaceutical sector inquiry report, the Commission monitored patent settlement agreements between originators and generic companies, in order to identify those settlements that delay generic market entry in breach of the competition rules. It

published eight annual reports, the last being for 2016, and appears to be no longer actively monitoring such settlements.

Patent settlement can be a legitimate way of ending a dispute or litigation relating to a potential breach of patent rights, but they can also be used by patent holders to implement strategies to delay or prevent the entry or expansion of the more affordable generic version of a drug in exchange for benefits transferred from the patent-holder (pay-for-delay agreements). The arrangement can benefit both the patent holder, which enjoys extended exclusivity resulting in extra profits and the generic-manufacturing company, which can make significant earnings without entering the market, but to the detriment of healthcare systems and patients who end up paying higher prices than they would have done in the event of independent generic entry.

As such agreements involve coordination between actual or potential competitors, they may be in breach of article 101(1) TFEU. The Commission has adopted infringement decisions in several pay-for-delay cases. In November 2020, the Commission fined Teva and Cephalon a total of €60.5 million for concluding a pay-for-delay settlement agreement that delayed the market entry of a generic version of Modafinil (a drug used for sleep disorders). The distinguishing feature of this case is that the arrangement went beyond lump sum payments and involved a wide range of 'side deals' (eg, a distribution agreement, access to valuable clinical data for another drug). The decision sends a clear signal that pay-for-delay agreements will not be tolerated irrespective of the form of the payments at issue and that the Commission will consider the cumulative effect of a range of commercial arrangements and deals. Teva appealed the Commission's decision to the General Court, which upheld the Commission's decision. Teva appealed this judgment to the Court of Justice of the EU (CJEU) (Case C-2/24 P). In March 2025 Advocate General Rantos issued his Opinion, summarising the case-law to date and concluding that the CJEU should dismiss the appeal. The CJEU's judgment is pending.

The Commission has also fined companies in other pay-for-delay cases, in relation to the drugs Citalopram, Perindopril and Fentanyl. On appeal against some of these decisions (and also in the Generics (UK) case), the EU courts' rulings have clarified the criteria and set out a framework for the assessment of pay-for-delay deals. The judgments confirm that, where the value transfer by the patent-holder to the generic cannot otherwise be justified (for example the net gain is in excess of the costs and disruption of litigation, or of remuneration for the actual supply of goods or services), the agreement at issue will be anticompetitive by its very nature (eg, 'by object'). The judgments also confirm that commercial arrangements (eg, distribution deals) may also constitute a value transfer to be assessed within this framework.

The latest CJEU judgment on a pay-for-delay case was in the ***Servier*** case, in June 2024. The CJEU largely upheld the Commission 2014 infringement decision imposing fines on Servier and several generic companies for entering into patent settlement and licence agreements held to amount to 'by object' restrictions of competition and, in the case of Servier, an abuse of dominant position. In reaching this conclusion, the CJEU overturned the earlier judgments of the General Court (GC) on two key points. First, the CJEU concluded that the settlement and licence agreements between Servier and Krka (one of the generic companies), amounted to a restriction of competition by object, finding that the GC had made a number of errors of law. It referred an assignment and licence agreement between these parties back to the GC for reconsideration. Second, the CJEU concluded that the GC had relied on 'incorrect grounds' when finding that the EC defined the relevant market too narrowly. The definition of the relevant market is key to determining whether Servier abused a dominant position via a

combination of settling patent disputes with generic challengers and 'killer acquisitions' of rival technologies. The CJEU therefore referred parts of the case back to the GC to reconsider the abuse of dominance infringement and the applicable fine.

Law stated - 20 May 2025

Joint communications and lobbying

To what extent can joint communications or lobbying actions be anticompetitive?

Unlike in the US, where joint lobbying is expressly excluded from the antitrust rules under the Noerr-Pennington doctrine (to the extent that such lobbying is not a mere sham to conceal an effort to interfere with legitimate competition), no such automatic safe harbour exists under EU competition law and it will be up to businesses to assess whether their conduct is competition compliant.

Particular risks in the context of trade associations or joint lobbying etc, are around the sharing of competitively sensitive information, or engaging in price fixing, customer or territorial allocation, bid rigging, collective boycotts and standard setting.

In ***EMC Development AB*** (Case T-432/05), the General Court recognised that normal lobbying activity carried out by a trade association that brings together companies in an industry in order to protect and promote the interests of its members is legitimate, but that joint lobbying may be anticompetitive where it influences a standard setting procedure to the extent of controlling it and undermining it. The Commission's horizontal guidelines also provide useful guidance on joint lobbying in the context of standard-setting.

Law stated - 20 May 2025

Public communications

To what extent may public communications constitute violation of antitrust laws?

Unilateral announcements by a company that are genuinely public, such as through a post on a publicly accessible website, statement in public or in a newspaper, generally do not constitute a concerted practice under article 101(1) TFEU.

However, there is a risk of competition law infringement if the announcement is in fact part of a concerted practice. The concern is that announcing future price increases may signal the intended market conduct of undertakings, and by reducing the level of uncertainty about their pricing behaviour, decrease their incentives to compete against each other. In its horizontal guidelines, the Commission clarifies that this may be the case where the market is concentrated and where there are high barriers to entry, and undertakings continuously publicise information without apparent benefit for consumers. (See Case AT.39850 ***Container Shipping***.)

In the pharmaceutical sector, the Court of Justice of the EU has held that the coordinated public communication of misleading information by pharmaceutical companies to favour the use of one drug over another may infringe article 101(1) TFEU.

In Case C-179/16 ***Hoffmann-La Roche and Novartis,*** it concluded that coordination between Novartis and Roche to communicate that the off-label use of a product was less safe than the on-label use of another product, to shift demand towards the more expensive product, was market sharing and a restriction of competition by object.

While previously 'disparagement' cases have been investigated at a member state level (notably but not only by the French Competition Authority), in 2024, the Commission issued two antitrust decisions relating to disparagement, indicating that this is an area of focus for the Commission.

In July 2024, it accepted commitments from Vifor Pharma, and on that basis closed its investigation in Case AT.40577 without a finding of infringement or sanction. The Commission reached a preliminary view that Vifor had abused a dominant position in national markets for intravenous iron treatment by carrying out a campaign of disparagement (by disseminating potentially misleading information) against its closest competitor in Europe. Vifor committed to:

- launch a comprehensive multi-channel communication campaign to correct and undo the effects of the previous potentially misleading messages;
- refrain from making any external promotional or medical communication, written or oral, about the safety profile of the competitor for a period of 10 years throughout the European Economic Area; and
- implement a number of measures and safeguards to ensure compliance, including internal mechanisms to ensure that all relevant external promotional and medical communications, as well as internal training materials, comply with the commitments prior to their use, as well as annual internal training of staff and a system of certification of compliance.

In October 2024, the Commission fined Teva €462.6 million for abuse of its dominant position in national markets for glatiramer acetate. The abuse consisted of misuse of the patent system and disparagement to delay a rival multiple sclerosis medicine. In relation to the latter, the Commission found that Teva had implemented a systematic disparagement campaign against a competing medicine, by spreading misleading information about its safety, efficacy and therapeutic equivalence with Teva's product Copaxone. Teva did so despite the relevant health authorities having approved the competing medicine and confirmed its safety, efficacy and therapeutic equivalence with Copaxone. Teva's disparagement campaign targeted key stakeholders, including doctors and national decision-makers for pricing and reimbursement of medicines, with the objective of slowing down or blocking the entry of the competing medicine. (Case AT.40588).

Law stated - 20 May 2025

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?

Disclosure requirements imposed on pharmaceutical companies under the sector's regulatory regime typically provide for the protection of commercially sensitive information and are therefore unlikely to increase the risk of anticompetitive exchanges of information. For example, the clinical trials Regulation (EU Regulation 536/2014), which launched a harmonised clinical trials information system in all EU and EEA member states (as of 31 January 2022), provides for the protection of commercially sensitive information. The EFPIA disclosure code, which requires member companies to disclose the transfers of value made to healthcare professionals and healthcare organisations, allows for disclosure of information on an aggregate basis where the information cannot be disclosed on an individual basis for legal reasons. The Heads of Medicines Agencies (HMA) and the European Medicines Agency have also produced a joint guidance document on the identification of commercially sensitive information that is provided under the marketing authorisation (MA) application regime and that must be protected.

Nevertheless, in any instance where competitively sensitive information may be received by a competitor the practice should be assessed for competition law compliance as the obligations, protections are likely to vary on a case-by-case basis.

Law stated - 20 May 2025

ANTICOMPETITIVE UNILATERAL CONDUCT

Abuse of dominance

In what circumstances is conduct considered to be anticompetitive if carried out by a firm with monopoly or market power?

Originators and patent-holders are entitled to protect the invention covered by the patent and thus the dominant position granted by it. However, conduct will be considered anticompetitive if it departs from 'competition on the merits'.

Over the years, the Commission has identified various practices that can be considered abusive under article 102 of the Treaty on the Functioning of the European Union (TFEU) when committed by dominant undertakings. These practices include:

- misleading representations before the authority in order to extend patent protection illegitimately (C-457/10 P, ***AstraZeneca v Commission***);
- selective deregistration of Marketing Authorisations (MA) with the object and effect of preventing entry by generics and/or parallel traders (C-457/10 P, ***AstraZeneca v Commission***);
- settlement agreements with generics to delay their entry into the market (C-307/18, ***Generics (UK) and others***);
- acquisition of alternative non-infringing production technologies and the conclusion of patent settlements as part of 'a single and continuous exclusionary strategy' (C-151/19 P, ***Servier***);
- excessive or unfair pricing (AT.40394, ***Aspen*** (closed by commitments));
- 'artificially' extending the market exclusivity of its patent by strategically filing and withdrawing divisional patents, repeatedly, delaying entry of generics that were forced to file a new legal challenge each time (AT.40588, ***Teva Copaxone***); and

- implementing a disparaging information campaign with the aim of reducing the use of competing drugs (exclusionary disparagement) (AT.40577, ***Vifor Pharma*** (closed by commitments) and AT.40588, ***Teva Copaxone***).

The Commission (and the Swiss competition authority) investigated whether Novartis had engaged in abusive litigation by deploying so-called blocking patents to prevent the use of other patents (and medicines embodying these patents) in the field of dermatological treatments. The Swiss authority's notes that the investigation revealed that Novartis' actions were common practice in the field of patent law and it did not find an infringement. In October 2024, the authorities therefore closed the investigation.

In March 2024, the Commission opened an investigation into Zoetis, a global animal health company, for allegedly abusing its dominant position by preventing the launch of a competing product. While this is not in the pharmaceutical sector, it relates to veterinary drugs and, therefore, there are strong parallels. Zoetis' Librela is the first and only monoclonal antibody medicine approved in Europe to treat pain associated with osteoarthritis in dogs. In parallel to developing Librela, Zoetis acquired another late-stage pipeline product for the same indication of pain relief, which was going to be commercialised in the EEA by a third party. The Commission is concerned that Zoetis may have engaged in exclusionary behaviour that could be an abuse of dominance by terminating the development of this alternative pipeline product and refusing to transfer it to the third party, which, in the EEA, had exclusive commercialisation rights. This is the first time the Commission has formally investigated a company for 'exclusionary termination of a pipeline product which was to be commercialised by a third party' (Case AT.40734).

In the wider life sciences sector, the Commission also has an investigation open into Edwards Lifesciences relating to allegations that its use of patents and a policy to stamp out 'copycat' products may be anticompetitive.

The Commission Guidance enforcement priorities in applying article 102 TFEU provide general guidance (not sector specific) on the Commission's approach to enforcing article 102. This Guidance is currently being revised. On 27 March 2023, the Commission amended the Guidance, introducing some changes to its enforcement priorities that are thought to somewhat allow the Commission more leeway to enforce more strictly under article 102. For example, the Commission notes that it is appropriate to clarify that the concept of 'anti-competitive foreclosure' refers 'not only to cases where the dominant undertaking's conduct can lead to the full exclusion or marginalisation of competition but also to cases where it is capable of resulting in the weakening of competition, thereby hampering the competitive structure of the market to the advantage of the dominant undertaking and to the detriment of consumers' and that:

> it is not appropriate to use the element of profitability of the dominant undertaking's conduct in order to determine the Commission's enforcement priorities, i.e. to pursue cases as a matter of priority only where the dominant undertaking can profitably maintain supra-competitive prices or profitably influence other parameters of competition, such as production, innovation, variety or quality of goods or services". Instead the anticompetitive foreclosure will now be defined as a situation "where the conduct of the dominant undertaking adversely impacts an effective competitive structure thus allowing the dominant undertaking to negatively influence, to its own

> advantage and to the detriment of consumers, the various parameters of competition, such as price, production, innovation, variety or quality of goods or services.

The Commission is planning to replace the Guidance completely by issuing new guidelines on exclusionary abuses of dominance. In August 2024, it published draft guidelines for consultation. It aims to adopt a final version of the guidelines in 2025.

Law stated - 20 May 2025

De minimis thresholds

Is there any de minimis threshold for a conduct to be found abusive?

There is no de minimis threshold to establish abuse under article 102 TFEU.

Law stated - 20 May 2025

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?

Both in merger cases and in antitrust investigations, the Commission conducts its market definition of relevant pharmaceutical markets according to the methodology set out in the Market Definition Notice (which was revised in February 2024). In merger cases, the Commission's start point is to consider level 3 of the Anatomical Therapeutical Chemical classification system (ATC) to define the relevant market, but it may look more narrowly at ATC level 4, molecule level or a bespoke definition.

In abuse of dominance cases, the Commission tends to define the market at the molecular level. This is particularly relevant to pharmaceutical companies and their legal advisors, as a narrow market definition increases the risk of a company being found to be dominant.

In its June 2024 judgment in ***Servier***, the Court of Justice of the EU (CJEU) upheld a 'narrow' approach to product market definition – in this case, molecule level, excluding those other products with the same therapeutic use. The concept of a relevant product market implies a 'sufficient degree of interchangeability between all the products'. The assessment of interchangeability cannot be assessed solely on the 'objective features' of the product (in other words, therapeutic quality). It also 'requires a determination as to whether, from an economic point of view, those products are in fact substitutable'. The CJEU went on to explain that the test for substitutability is whether a small but permanent price increase would lead consumers to switch to a substitute product. Applying this to pharmaceutical products, the CJEU stated that this is the case 'irrespective of the specific characteristics of the pharmaceutical sector which are associated with the applicable legislation, with the role of prescribing doctors and with the fact that the price of medicinal products is covered by insurance mechanisms' (C-176/19 P).

Moreover, as the CJEU held in ***Generics (UK) and others*** (C-307/18), the Commission must take into account generic versions of a medicine when defining the relevant market, provided that the generic market entry does not meet insurmountable barriers.

Law stated - 20 May 2025

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 EU courts have defined dominance as 'a position of economic strength enjoyed by an undertaking [that] enables it 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, customers and ultimately of its consumers'. In practice, the Commission considers high market shares (40 per cent or above) maintained over a long period as the main factor to establish dominance. However, it considers other factors, such as the relative market shares of competitors, existence of barriers to entry or expansion, first-mover advantage and incumbency, possession of key technology, economic strength, etc.

In the pharmaceutical sector in particular, IP rights are perceived as an important barrier to entry and/or expansion and may in themselves give rise to a dominant position. This is because competitors and potential new entrants may not be able to manufacture or market the same products during the period of protection without infringing the patent. However, as the Court of Justice of the EU confirmed in ***Servier*** (C-176/19 P), the Commission must consider other factors, as well as the IP rights, in particular whether, from an economic point of view, there is potential interchangeability between the relevant molecule and other treatments.

Joint dominance is possible where two or more legally independent parties have strong legal, organisational or contractual links such that they are able to adopt a common policy on the market. The Commission may also consider other factors, such as market conditions, level of transparency, barriers to entry, etc.

Law stated - 20 May 2025

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?

Originators and patent-holders have the right to obtain and enforce patents or other IP rights to protect the invention covered by their patent. However, in exceptional circumstances, the grant or enforcement of IP rights may constitute an abuse of dominance if it forms part of an overall strategy with a clear anticompetitive aim.

In a landmark case, the Commission found that AstraZeneca's SPC applications before several patent offices constituted an abuse of dominance, as it had submitted incorrect and

misleading information to obtain protection and thus prolong its market dominance. The CJEU upheld the decision (C-457/10 P*AstraZeneca*).

More recently, in another landmark case, in October 2024 the Commission fined Teva €462.6 million for abuse of dominance by strategic filing and withdrawing applications for divisional patents with the sole purpose of delaying market entry by generics, who were forced to file a new legal challenge each time (Case AT.40588). The Commission found that when its patent protecting glatiramer acetate was about to expire, Teva artificially extended Copaxone's patent protection by misusi'ng the European Patent Office's (EPO) rules and procedures on divisional patents. While divisional patent applications are an otherwise legitimate practice, Teva filed multiple divisional patent applications in a staggered way, creating what the Commission refers to as a 'web of secondary patents around its product Copaxone, focusing on the manufacturing process and dosing regimen. Competitors challenged these patents to clear the way to the market. Pending review by the EPO, Teva started enforcing these patents against competitors to obtain interim injunctions. When the patents seemed likely to be revoked, Teva strategically withdrew them, to avoid a formal invalidity ruling, which would have set a precedent that the Commission considered would have threatened its 'other divisional patents to fall like dominos' (it also noted that all Teva's divisional patents had eventually been annulled). By doing so, Teva forced competitors to repeatedly start new lengthy legal challenges. This tactic allowed Teva to artificially prolong legal uncertainty over its patents and, potentially, hinder the entry of competing glatiramer acetate medicines.

Law stated - 20 May 2025

IP rights

When would life-cycle management strategies expose a patent owner to antitrust liability?

Patent owners have the right to enforce and secure the protection of their inventions for which they have a valid patent. However, various practices may be considered abusive when they result in a deviation from competition on the merits. These abusive practices can take a variety of forms.

For example, the Commission found that AstraZeneca had abused its dominant position through selective deregistration of its marketing authorisations (MA) in those countries where generic companies had applied for MAs, thereby preventing the generics from using a simplified procedure to obtain authorisations (C-457/10, P AstraZeneca).

Most recently, in October 2024, the Commission fined Teva €462.6 million for abuse of dominance consisting of denigration of a competing product, and of strategic filing and withdrawing applications for divisional patents with the sole purpose of delaying market entry by generics, who were forced to file a new legal challenge each time (Case AT.40588).

National competition authorities have investigated other types of anticompetitive practices in lifecycle management, such as exclusivity rebates offered to hospitals to prevent generic entry, and predatory pricing practices.

Law stated - 20 May 2025

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

Generic manufacturers have often complained that exclusionary disparagement tactics create barriers to market entry for them, making it difficult to compete with patent-holders' drugs despite patent expiry for the active ingredient.

The Commission and Court of Justice of the EU have concluded that the provision of misleading information to consumers or the medical sector may constitute an abuse of dominance (see C-457/10 P*AstraZeneca*, and C-179/16 *Hoffmann-La Roche and Novartis*).

In 2024, the Commission issued two antitrust decisions relating to disparagement, indicating that this is an area of focus for the Commission.

In July 2024, it settled an investigation into Vifor Pharma with commitments (Case AT.40577). The Commission had reached a preliminary view that Vifor had abused a dominant position in national markets for intravenous iron treatment by disseminating potentially misleading information against its closest competitor in Europe. In particular, it considered certain communications primarily targeting healthcare professionals (HCPs) to be objectively misleading and not reflective of competition on the merits, as they were based on inaccurate and/or incomplete information not supported by appropriate scientific evidence, which was presented in a manner that was capable of confusing HCPs, instilling doubts in their minds as to the competing product's safety. The Commission's view was that these messages were capable of creating a negative perception of the competing product's safety and, as such, of discrediting it in the eyes of HCPs. The Commission considered that these messages were capable of producing exclusionary effects and had no objective justification. Therefore, Vifor's practices may have hindered market entry and/or market uptake of the competing product, raising concerns that it was an abuse of dominance.

In October 2024, the Commission fined Teva €462.6 million for abuse of its dominant position in national markets for the use of glatiramer acetate to treat multiple sclerosis (Case AT.40588). The infringement covered two abuses, the second of which consisted of disparagement. Specifically, the elements of the abuse were:

- that Teva disseminated objectively misleading information on key features of a competing product capable of discrediting it (namely questioning its safety, efficacy and therapeutic equivalence with Teva's product Copaxone);
- that Teva put in place effective mechanisms for the dissemination of the objectively misleading messages to relevant stakeholders (national authorities competent for pricing and reimbursement, health insurance funds and healthcare professionals) in the seven relevant member states;
- that this conduct was capable of producing exclusionary effects; and that
- it was not objectively justified.

The objectively misleading information in question concerned three different types of messages that ran against the regulatory findings of the competent medicines agencies in the EU. More precisely, these messages consisted of:

-

emphasising clinically irrelevant differences in molecular structures of Copaxone and the competing product GA;

- pointing to the risks observed in the use of other glatiramer-related substances, unjustifiably implying that they equally applied to the competing product; and
- calling into question the scientific validity of the study on which the competent authorities based their finding of therapeutic equivalence between Copaxone and the competing product.

Law stated - 20 May 2025

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?

Subject to the provisions in article 82(1), second subparagraph, of Regulation (EC) No. 726/2004, a patent owner may under some conditions submit more than one marketing application with a view to co-marketing a medicine. Gaining a head start on the competition would not be an infringement by the originator or a third party that is licensed under the patent. However, if the sole aim of the practice is to prevent or delay the entry of other generics to the market this could constitute an abuse of dominance.

Law stated - 20 May 2025

Restrictions on off-label use

Can actions taken by a patent owner to limit off-label use trigger antitrust liability?

Actions taken by a patent owner to limit off-label use can trigger antitrust liability. For example, in ***Hoffmann-La Roche and Novartis*** (C-179/16), the CJEU held that the agreement between Roche and Novartis, intended to disseminate misleading information relating to adverse reactions resulting from the off-label use of a medicine, constituted a restriction of competition 'by object'.

Law stated - 20 May 2025

Pricing

When does pricing conduct raise antitrust risks? Can high prices be abusive?

Patent owners are free to set prices provided that, if the company is in a dominant position, it does not foreclose competitors or exploit consumers.

Setting predatory prices (ie below costs), may constitute an exclusionary abuse of a dominant position under article 102 TFEU. In ***AKZO*** (C-62/86), the CJEU set out a two-step

test whereby (1) prices are presumed to be predatory if they are set below average variable costs, and (2) if prices are set below average total costs but above variable costs, it will be necessary to prove additional elements to establish an anticompetitive intent. Although the Commission has not to date pursued any cases in the pharmaceutical sector, an exclusivity rebate policy implemented by a patent owner in a dominant position could be considered abusive (there have been such cases at a national level; see, for example, in the Netherlands).

Excessive pricing may be an abuse of a dominant position. In May 2017, the Commission launched a formal investigation into Aspen's excessive pricing conduct – the first excessive pricing investigation by the Commission in the pharmaceutical sector. It closed the investigation in February 2021 when it accepted legally binding commitments offered by Aspen, which removed its concerns. Under the commitments Aspen agreed to reduce its prices across Europe for each of the drugs involved by an average of 73 per cent, thereby reducing the prices to below 2012 levels, when it acquired the drugs and gradually started to increase prices.

Law stated - 20 May 2025

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?

In ***GlaxoSmithKline*** (Joined cases C-501/06, C-213/06, C-515/06 and C-519/06), the CJEU held that pricing restrictions on parallel trade in the pharmaceutical sector had as their object the restriction of competition, but that the Commission should have assessed a possible exemption under article 101(3) taking into account the arguments put forward by GSK in relation to the specific nature of competition in the pharma sector. GSK had argued that its pricing strategy did not restrict competition because the price differences between member states resulted from national price regulations. It claimed that there were consumer welfare arguments for justifying a restriction on competition, referring to the losses suffered as a consequence of parallel trade, which affected its R&D budget for developing new and innovative drugs. The Commission should have taken these arguments into account but had failed to do so.

Law stated - 20 May 2025

UPDATES AND TRENDS

Recent developments

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

The pharmaceutical sector has long been a focus of the Commission's enforcement activity, which has recently reaffirmed its aim to ensure innovation and competition in the sector.

Pay-for-delay agreements remain in the spotlight, with the Court of Justice of the EU (CJEU)'s recent ruling in ***Servier*** shedding further light on the Commission's approach to

such agreements as restrictions of competition by object, as well as on market definition. Advocate General Rantos subsequent March 2025 Opinion in ***Teva/Cephalon*** summarises the framework for analysis of such cases, and the CJEU's judgment in that case is pending.

The Commission is also widening its scope of intervention in the pharmaceutical sector. In particular, in 2024 the Commission concluded two cases concerning abuse by dominance by disparagement campaigns against competitors (***Vifor Pharma*** and ***Teva/Copaxone***), the first such cases brought by the Commission.

In another 'first', it found that Teva had abused a dominant position by artificially extending its patent protection by misusing the process by the way in which it applied for and litigated divisional patents (which the Commission refers to as the 'divisionals game'). ***Teva/Copaxone*** is an important case given that companies in the pharmaceutical sector regularly apply for, challenge and defend patents. The Commission found an infringement on the basis that Teva had filed multiple divisional patent applications in a staggered way, creating a web of secondary patents around Copaxone focusing on the manufacturing process and the dosing regimen of glatiramer acetate. Rivals challenged these patents to clear the way to the market. Pending review by the European Patent Office, Teva started enforcing these patents against competitors to obtain interim injunctions. When the patents seemed likely to be revoked, Teva strategically withdrew them, to avoid a formal invalidity ruling, which would have set a precedent threating other divisional patents to fall like dominos (all the relevant divisional patents have now been annulled). By doing so, Teva forced competitors to repeatedly start new lengthy legal challenges. Therefore, while divisional patent applications are an otherwise legitimate practice, Teva's behaviour allowed it to artificially prolong legal uncertainty over its patents and, potentially, hinder the entry of competing medicines. Teva has appealed the Commission's decision.

Whilst the Commission settled the ***Vifor Pharma*** case, its willingness to issue high fines where it finds an infringement of competition law is demonstrated by the €462.6 million fine imposed on Teva for the infringements in ***Teva/Copaxone***.

In the wider life sciences sector, the Commission has an investigation open into Edwards Lifesciences relating to allegations that its use of patents and a policy to stamp out 'copycat' products may be anticompetitive. In relation to the neighbouring sector of veterinary drugs, the Commission has an investigation open into Zoetis for exclusionary termination of a pipeline product that was to be commercialised by a third party.

The outcomes of these investigations have important consequences for how pharmaceutical companies can manage their patent prosecution and other life-cycle strategies.

Another notable development is that the Commission imposed its first cartel sanction in the pharmaceutical sector (***SNBB***), settling with six of the parties in October 2023 (with fines totalling €13.4 million), and in June 2024 issuing a Statement of Objections against Alchem (which was not part of the settlement). The behaviour at issue in that case was coordinating and agreeing to fix minimum sales prices (price fixing), allocating quotas (market sharing), as well as the exchange of commercially sensitive information.

As for merger control, the Commission is actively seeking to protect innovation in its merger reviews, including by seeking jurisdiction under article 22 EU Merger Regulation (EUMR) to catch 'killer acquisitions' falling below the relevant EU or national thresholds. The CJEU recently overturned the Commissions' use of article 22 in cases where the referring member

state did not have jurisdiction to review the case (***Illumina/Grail***), leading to the Commission withdrawing its guidance on the use of article 22. However, the Commission considers that it can still accept such cases where the referring member state has jurisdiction to review the merger under 'call-in' powers (where, despite not meeting the thresholds, the merger threatens to affect competition), or where a member state's thresholds are met on the basis of market shares or size of transaction. The Commission's power to do so on the basis of a member state's 'call-in' powers has been challenged in the courts in ***Nvidia/Run:ai***. The Commission is also considering amendments to the thresholds in the EU Merger Regulation, but there is no consensus for this. In addition, the ***Towercast*** judgment of the CJEU confirms that article 102 TFEU can be used to challenge acquisitions otherwise falling below merger control thresholds, with the Advocate General in that case explicitly referring to there otherwise being 'a gap in protection … in the coverage and control, under competition law, of acquisitions of innovative start-ups, for example, in the fields of internet services, pharmaceuticals or medical technology (killer acquisitions)'. Therefore the ***Illumina/Grail*** judgment does not mean that acquisitions in the pharmaceutical sector of companies with low turnover will escape review, and if anything has complicated parties' risk analysis of whether, and where, their transactions will be subject to review.

In May 2025, the Commission launched a review of both its horizontal merger guidelines and non-horizontal merger guidelines. Its review, which will lead to revised guidelines, is focusing on how the Commission's assessment of mergers should give adequate weight to areas including innovation, efficiency, resilience, investments, intensity of competition in certain strategic sectors, sustainability and other transformational needs of the European economy. The changes in the guidelines are therefore likely to be highly relevant to companies in the pharmaceutical sector.

The focus on these topics reflects the Letta report (April 2024) into the EU single market, and the Draghi report (September 2024) into competitiveness in the European economy. The Draghi report in particular identifies 'a slow and complex EU regulatory framework' as one of the multiple causes that underpin the EU's emerging competitive gap. It also calls for a new approach to competition policy supporting a new 'industrial deal', and calls for a more innovation-oriented approach. These reports were influential in the workplan of the new European Commission, which started its five-year mandate on 1 December 2024 (eg, the Competitiveness Compass published in January 2025). Teresa Ribera is the new leader of DG Competition, as Executive Vice-President for Clean, Just and Competitive Transition. She takes over at an important time for antitrust enforcement and modernisation of EU competition policy. Her 'mission letter' also reflects the need for a focus on innovation and reform. The pharmaceutical sector will undoubtedly likely remain under close scrutiny from the Commission, and be affected by the ongoing modernisation of competition law.

Law stated - 20 May 2025