EU and UK merger control in the pharmaceutical sector

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A practice note providing a general overview of the EU and UK merger control regimes and a discussion of issues that are of particular relevance to the pharma sector, including market definition, price and innovation effects of horizontal mergers, and remedies.

Scope of this note

The pharmaceutical sector has seen considerable consolidation in recent years, including a number of transactions valued in the tens of billions of dollars. Some of the most significant acquisitions in recent years include Takeda's $62 billion acquisition of Shire and Bristol-Myers Squibb's $74 billion purchase of Celgene.

At the same time, competition law enforcement in the sector has been a high priority across the EU since the European Commission's 2009 sector inquiry. In a report published in January 2019, the Commission emphasised that "effective

enforcement of EU competition rules in the pharmaceutical sector remains a matter of high priority and the competition authorities will continue to monitor and be pro-active in investigating potential anti-competitive situations" (*Commission: Report on Competition enforcement in the pharmaceutical sector (2009-2017), page 4*). In addition, the UK's Competition and Markets Authority (CMA) said it would "continue to have a strong focus on the UK pharmaceutical sector, to ensure that the NHS does not pay significantly more than it should for essential medicines and treatments, and that consumers who depend upon these drugs and treatments do not lose out" (*CMA: Competition and Markets Authority Annual Plan 2020/21, paragraph 3.10*). While these statements arguably apply mainly to enforcement of the competition rules on anti-competitive agreements and abuse of dominance, it is reasonable to consider that the authorities will have a similarly strong focus on the pharma sector in the area of merger control.

Pharma companies pursue M&A transactions to achieve economies of scale, extend research and development (R&D) to new therapeutic areas, meet increased profit targets, and so on. Consolidation in the sector may be pro-competitive if, for example, it combines merging firms' complementary activities and strengthens their ability and incentive to bring innovative products to the market. In some cases, however, consolidation has the potential to weaken competition. The objective of merger control is to prevent those mergers that are likely to deprive consumers of the benefits of competition.

The European Commission analysed more than 80 mergers in the pharma sector in the years 2009-2017. Of those, 19 were deemed to be problematic from a competition standpoint. The Commission's "intervention rate" in the pharma sector, calculated by comparing the number of merger prohibitions, merger approvals subject to remedies, and withdrawals of a merger notification in Phase II, to the overall number of cases notified to the Commission, in this period was roughly 22%, which was significantly higher than its average intervention rate across all sectors of 6% (*Commission: Report on Competition enforcement in the pharmaceutical sector (2009-2017), page 14*). In the UK, cases such as the merger between Roche Holdings and Spark Therapeutics suggest that the CMA is taking an increasingly expansive approach to jurisdiction in merger control, particularly in dynamic sectors such as pharma, which involve "challenger" firms and high levels of innovation (*CMA decision: Roche/Spark Therapeutics (ME/6831/19)*).

This practice note provides a general overview of the EU and UK merger control regimes and focuses on certain issues that are of particular relevance to the pharma sector, including market definition, price and innovation effects of horizontal mergers, and remedies.

Overview of EU and UK merger control regimes

EU regime

The European Commission has power under the *EU Merger Regulation (139/2004/EC)* (EUMR) to examine significant cross-border M&A, and to prohibit them when

they are incompatible with the internal market (for example, because they would significantly impede effective competition in all or a substantial part of the internal market, in particular as a result of the creation or strengthening of a dominant position). The EUMR applies to any "concentration" with an "EU dimension". The concept of concentration is broadly defined to cover not just mergers and acquisitions of control, but also the creation of "full-function" joint ventures (see *Practice note, EU mergers and acquisitions: What is a concentration?*). A transaction has an EU dimension when certain turnover thresholds are satisfied (see *Practice note, EU Mergers & acquisitions: EU dimension*).

Generally, the European Commission has exclusive jurisdiction over concentrations with an EU dimension. Transactions that are subject to review by the Commission under the EUMR are not, as a general rule, subject to parallel inquiries under the national merger control rules of member states (see *Practice note, EU mergers and acquisitions: One-stop shop principle*). Articles 4, 9 and 22 of the EUMR provide for procedures that allow jurisdiction to be transferred between the Commission and the national competition authorities of member states in certain circumstances (see *Practice note, EU mergers and acquisitions: Referral back to member states and Referral to the Commission*). As discussed in more detail below in *Jurisdictional aspects of EU merger control: the Article 22 referral mechanism*, in March 2021 the Commission issued new guidance on the Article 22 referral mechanism, encouraging national competition authorities to refer certain transactions to the Commission for review even where they do not meet the EU or national merger control thresholds.

Concentrations falling within the scope of the EUMR must be notified to the European Commission and generally cannot be implemented unless the Commission determines that they are compatible with the internal market. Once a proposed transaction is formally notified, the Commission typically has 25 working days to make its initial, Phase I assessment of whether the transaction can be expected to "significantly impede effective competition" in the internal market (see *Practice note, EU Mergers & acquisitions: Commission's assessment*). If the Commission decides to open in-depth, Phase II proceedings (which happens in a minority of cases), it will have at least 90 working days to complete its investigation. At the end of the Phase II period, the Commission may either clear the transaction (unconditionally or subject to "commitments") or prohibit it.

Brexit

The relationship between the EU and UK merger control regimes has now changed as a result of Brexit.

Since the transition period ended on 31 December 2020, the one-stop shop principle no longer applies as far as the UK is concerned. There are likely to be increasing numbers of parallel reviews of transactions by the European Commission and the CMA, and some mergers may fall outside the scope of the EUMR altogether as a result of UK turnover no longer counting towards the EU turnover thresholds.

The CMA's merger control workload has increased significantly since the UK left the EU, as the CMA now has jurisdiction over many more transactions and can review deals in parallel with the European Commission. As discussed further below, the CMA has in recent years also become more interventionist in its approach to merger control, including in the pharma sector.

UK regime

The UK merger control rules are contained in the *Enterprise Act 2002*. Generally, mergers qualify for review under the UK rules if either of the following tests is satisfied:

- The "turnover test": the UK turnover of the business being acquired exceeds £70 million.
- The "share of supply test": the transaction results in the creation or enlargement of a share of at least 25% of the supply or purchase of goods or services of a particular description in the UK or a substantial part of it.

For more information, see *Practice note, UK Mergers and acquisitions: Relevant merger situation*.

The share of supply test is not a market share test: it is not necessary to define the relevant product and geographic markets to determine whether the test is satisfied. The CMA has a wide discretion to describe the relevant goods or services, and to choose the criteria for determining whether the 25% threshold is met. In *Roche/Spark Therapeutics*, the merger was deemed to meet the share of supply test even though the US-based target, Spark, was not engaged in the commercial supply of any goods or services in the UK and did not generate any other UK turnover. The CMA found that Spark's global R&D activities relating to the **potential** treatment of haemophilia A (Hem A) in the UK contributed to the supply of goods or services in the UK, on the basis that advanced-stage R&D activities are integral to the process of supplying pharma treatments. It also found that the 25% threshold was satisfied on the basis of the number of UK-based employees engaged in activities relating to the treatment of Hem A and the number of UK and EU patents held by the parties relating to the treatment of Hem A. For further analysis of the CMA's decision, see *Legal update, CMA full text decision on Roche Holdings / Spark Therapeutics merger*.

Unlike under the EUMR, there is no system of mandatory notification and clearance in the UK. In practice, however, mergers are often notified on a voluntary basis, usually before completion. The CMA has the power to review mergers regardless of whether they are notified and has a dedicated Mergers Intelligence Committee that monitors UK merger activity. If the CMA hears about a non-notified merger, whether through being informed via a third party bringing the transaction to its attention or through its own monitoring of the financial press, it may choose to contact the parties and ask them for the information necessary to establish whether the jurisdictional thresholds are satisfied and to assess the merger's impact on competition.

Transactions that meet the jurisdictional thresholds may be assessed by the CMA in an initial Phase I investigation (whose assessment period is 40 working days). The CMA

must refer a transaction for an in-depth Phase II investigation if it considers that the transaction may result in a "substantial lessening of competition" (SLC) on the market(s) in question. The SLC test is effectively the same as the substantive test under the EU merger regime and is applied by the CMA at both Phase I and Phase II. At Phase I, the CMA applies the "reasonably held belief" test. At Phase II, the threshold is higher as the CMA decides based on a balance of probabilities (that is, whether an SLC is more likely than not). The Phase II investigation may result in a prohibition decision, a decision that the merger may proceed subject to commitments, or clearance.

Recent decisional practice suggests that, as well as taking an expansive approach to jurisdiction, the CMA is now taking an increasingly thorough approach to Phase I investigations and is also referring a higher proportion of deals to Phase II. In the year to March 2022, 18% of all mergers assessed by the CMA in Phase I were referred for a detailed investigation, compared with an average of 13% in the years 2015-2018. And in 75% of Phase II cases in the year to March 2022, the transaction did not go ahead as originally notified, either because of abandonment, remedies, or prohibition (*CMA: Annual Report and Accounts 2021/2022*, page 9).

Particularities of the pharma sector

Competition authorities recognise that for their antitrust enforcement and merger control in the pharma sector to be effective, they need to take account of the particularities, and resulting competitive dynamics, of the sector. These particularities include:

- **Specific structures of demand and supply (involving a wide variety of stakeholders).** The demand side in pharma markets is shaped by a number of stakeholders whose interests are not necessarily aligned: patients; doctors (who are responsible for effective treatment of patients but not for the cost); and national and private health insurance schemes (which seek to ensure medicine expenditure is sustainable). The supply side is characterised by manufacturers with various business models (supplying originator medicines, generic medicines or both); wholesalers; and different types of pharmacies.
- **Comprehensive legislative and regulatory frameworks.** The pharma sector is highly regulated. As well as fulfilling marketing authorisation requirements, manufacturers typically have to undergo pricing and reimbursement procedures before marketing prescription drugs. UK and EU member state pricing and reimbursement rules can have a significant impact on competition between such drugs. Over-the-counter (OTC) products are subject to different competitive dynamics. They are less subject to reimbursement rules and prescription guidance, which shifts the decision-making role to end-users and pharmacies. Success of OTC products tends to rely more on advertising and branding strategies.
- **High levels of R&D and innovation.** The pharma sector is one of the most R&D-intensive in the world. Innovation is driven by demand for new, more effective and safer treatments for patients and the threat of competition (especially generic competition after loss of exclusivity). Development cycles for innovative drugs are typically risky and lengthy, and entail high development

costs. Only a small minority of candidate drugs survive the development stage and finally make it to market.

- **Exclusivity mechanisms.** Given the high development costs and the fact that, once a new drug has been developed, it is relatively simple for rivals to copy, legislation grants originator firms exclusivity mechanisms which are designed to incentivise investment in R&D. Examples of such mechanisms include intellectual property rights (such as patents and supplementary protection certificates), regulatory data protection and market exclusivity. For more information, see *Practice notes, Overview of IP issues in health and life sciences* and *EU regulatory data protection for life sciences companies*.

Substantive merger assessment in the pharma sector

Substantive merger assessment generally

Although jurisdictions apply different legal tests and procedures for assessing mergers, substantive merger assessment is typically based on broadly accepted economic principles, giving rise to commonalities in the legal and economic assessment across jurisdictions. The focus of the enquiry is on whether the merger in question is likely to result in market power and anti-competitive effects. The specific issues that need to be considered will, however, depend on the nature of the merger in question:

- **Horizontal mergers** are mergers between actual or potential competitors that operate at the same level of the supply chain.
- **Vertical mergers** involve firms operating at different levels of the supply chain (for example, a manufacturer of an active pharmaceutical ingredient and a supplier of a finished pharmaceutical product).
- **Conglomerate mergers** involve firms that are not active in the same market (either horizontally or vertically), but are present in different, and often related, markets.

This practice note focuses on horizontal mergers, as these are the ones that most frequently give rise to competition concerns.

Issues of market definition

Before assessing whether a merger raises substantive issues, it is necessary to identify the various competitive constraints faced by the firms involved. Generally, the starting point is identifying competitive constraints to define the scope of the relevant market(s) in which the firms operate. In a merger context, market definition helps competition authorities assess the extent to which the merged entity will enjoy market power. However, given the difficulties in defining markets accurately, competition authorities often decline to reach a definitive view on the scope of the relevant markets in first-

stage merger inquiries, instead considering whether concerns would arise if different definitions were adopted.

The relevant market comprises both:

- A product dimension: which other products exert significant competitive pressure on the product in question?
- A geographic dimension: in which geographic area is the competitive pressure exerted?

To understand which products belong to the same market, both demand-side substitution (for example, whether prescribers and patients would readily switch from one product to another) and supply-side substitution (for example, whether there are suppliers that could switch to producing a specific drug) need to be considered.

Market definition for prescription drugs

For prescription drugs, competition authorities typically take account of the Anatomical Classification system devised by the European Pharmaceutical Market Research Association (EphMRA) when assessing the relevant product market. The system, sometimes referred to as the "Anatomical Therapeutic Classification" (ATC) system, divides medicinal products into five different levels:

- First level (ATC1): main anatomical groups.
- Second level (ATC2): either a pharmacological or therapeutic group.
- Third level (ATC3): therapeutic indication (that is, intended use).
- Fourth level (ATC4): mode of action.
- Fifth level (ATC5): specific molecule.

In a merger context, the European Commission and the CMA typically take ATC3 as their starting point for assessment. However, other ATC levels may also be taken into consideration where it appears that sufficiently strong competitive constraints operate at those levels.

The Commission has in recent years tended to define pharma markets narrowly, particularly in cases involving generics or biosimilars (see, for example, *Teva/Allergan Generics* (*Case M.7746, decision of 10 March 2016*) and *Pfizer/Hospira* (*Case M.7559, decision of 4 August 2015*). The General Court's judgment in *Servier* represented something of a setback to the Commission's preference for narrowly defined pharma markets (*Les Laboratoires Servier v Commission (Case T-691/14) EU:T:2018:922*), suggesting that competition authorities should take sufficient account of both price and non-price factors when defining the market in pharma cases and emphasising the importance of therapeutic substitutability and doctors' decision-making. However, the General Court’s judgment was appealed to the European Court of Justice and

in the (non-binding) Opinion of 14 July 2022, Advocate General Kokott considered that the General Court provided inadequate reasoning in annulling the part of the Commission's decision regarding the definition of the relevant market for the purpose of applying Article 102 TFEU (Les Laboratoires Servier v Commission (Case C-201/19 P) EU:C:2022:576). For further details of the status of the case, see *C-201/19 P - Servier and Others v Commission*.

On 8 November 2022, the Commission issued a draft revised Market Definition Notice (Draft Notice) for consultation. The Draft Notice provides new specific guidance on defining markets in innovation-heavy sectors such as pharma, recognising the need to take account of the "specific factors" in industries characterised by frequent and significant investments in R&D. It states that the Commission may take into account "expected transitions in the structure of a market" if the case in question requires a forward-looking assessment. In a pharma context, the Draft Notice suggests that the relevant product market may be widened to include "pipeline" products that are currently undergoing clinical trials (pipeline products are discussed further below); and that, alternatively, the relevant product market may be narrowed to only a specific molecule in cases where entry of a generic version of an originator product is imminent.

Market definition for OTC medicines

Branding and advertising often play a significant role in the success of OTC medicines. Consumers also tend to base their decision-making more on labelled indication, format and price than on the active ingredient, which is more relevant for prescription drugs. Given these differences, use of the ATC system has certain limitations in cases involving OTC medicines. In *Ciba-Geigy/Sandoz* (*Case IV/M.737, decision of 17 July 1996*), the European Commission declined to follow the ATC classification, instead basing its OTC market analysis on consumers' requirements. Similarly, in *Sanofi/Boehringer Ingelheim Consumer Healthcare Business* (*Case M.7919, decision of 4 August 2016*), the Commission attached importance to brand recognition, labelled indication and price in its assessment of the relevant product markets, stating that "the ATC and active ingredient based approach to market definition has significant limitations in an OTC context".

Innovation markets and "pipeline" products

In innovation-heavy sectors such as pharma, a merger may affect competition in innovation and future product markets as well as existing markets. This may be the case when a merger involves firms currently developing new products or technologies which may at some point replace existing ones, or which are being developed for a new intended use and will, therefore, not replace existing products but create an entirely new demand. In such scenarios, a full substantive analysis requires examination of those products that have not yet entered the market but are in clinical development (often referred to as "pipeline" products). Cases such as *Novartis/GSK Oncology Business* (*Case M.7275, decision of 28 January 2015*) and *Pfizer/Hospira* suggest that the Commission typically takes an expansive approach to assessing potential competition in pharma merger investigations, examining not just products that are in Phase III clinical trials but also pipeline products in earlier stages of development.

"Non-co-ordinated" effects of horizontal mergers

Horizontal mergers between existing competitors generally give rise to the most significant competition risks, as they involve the removal of an actual competitor in the same market. However, mergers that remove a potential competitor may also raise competition concerns, particularly where there are indications that competition in the relevant market is already ineffective and the target is one of a small number of potential entrants.

"Non-co-ordinated" (or "unilateral") effects arise where a significant competitive constraint is eliminated by the merger, with the result that the merged entity could unilaterally and profitably increase prices or otherwise behave anti-competitively (for example, by reducing output, quality, choice of products, or levels of innovation). This practice note focuses on two main categories of non-co-ordinated effects in a pharma merger context: price effects and innovation effects:

- **Price effects.** As the European Commission sees it, "a key objective of merger control in the pharmaceutical sector is to ensure that the changes in the market structure due to a merger do not result in higher prices" (*Commission: Report on Competition enforcement in the pharmaceutical sector (2009-2017), page 35*). A merger may lead to higher prices if the market power of the merged entity is increased. Generally speaking, the greater the market power arising from the merger, the more likely it is to result in higher prices (and therefore in harm to patients and healthcare systems).

  In recent years, the Commission has intervened in several pharma mergers that could have resulted in higher prices, particularly for generic and biosimilar products. In *Teva/Allergan*, which involved the first and fourth largest generics manufacturers in the world, the Commission found that the merger would have adversely affected price competition in several countries of the European Economic Area (EEA). In the UK, the Commission's investigation revealed that Teva and Allergan were the only firms capable of selling their generic drug portfolios directly to pharmacies (all other generic manufacturers had to sell through wholesalers). This led the Commission to conclude that Teva and Allergan exerted unique pricing pressure on each other in their dealings with pharmacies. To address the Commission's concerns, the companies agreed to divest the majority of Allergan's generics business in the UK and Ireland.

  In *Pfizer/Hospira*, the Commission found that the proposed merger would have brought two biosimilar versions of infliximab under Pfizer's ownership (Hospira's Inflectra product and Pfizer's biosimilar which was still under development). Before the merger, only one infliximab biosimilar had been launched and was co-marketed independently by Celltrion (under the brand name Remsima) and by Hospira (under the brand name Inflectra). The Commission considered that the transaction would reduce future price competition in the event that Pfizer discontinued the development of its own pipeline biosimilar, since new entrants have to price aggressively to gain market share from established suppliers. Alternatively, Pfizer might have decided to prioritise the development of its own biosimilar and hand back Hospira's product to Celltrion, thereby removing existing price competition between Hospira's Inflectra and Celltrion's Remsima.

In either case, the merger was likely to result in a softening of price competition, and the Commission therefore accepted Pfizer's commitment to divest its pipeline biosimilar drug.

Teva/Allergan and *Pfizer/Hospira* are just two of several cases in which the Commission has identified concerns over potential price increases. The Commission has intervened on price grounds in mergers between:

- originator companies (for example, *GSK/Novartis Vaccines Business* (*Case M.7276, decision of 28 January 2015*));
- generics companies (for example, *Teva/Ratiopharm* (*Case M.5865, decision of 3 August 2010*), *Teva/Barr* (*Case M.5295, decision of 19 December 2008*), *Mylan/Abbott EPD-DM* (*Case M.7379, decision of 28 January 2015*)); and
- originator and generics companies (for example, *Sanofi-Aventis/Zentiva* (*Case M.5253, decision of 4 February 2009*), *Teva/Cephalon* (*Case M.6258, decision of 13 October 2011*)).

- **Innovation effects.** Competition authorities recognise that mergers may result in synergies that help to stimulate innovation (for example, by combining complementary assets required to engage in R&D). In some circumstances, however, a merger may have adverse effects on the merged entity's incentives to innovate. The European Commission's Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings state that "effective competition may be significantly impeded by a merger between two important innovators, for instance between two companies with 'pipeline' products related to a specific product market" (*Horizontal Merger Guidelines, OJ 2004 C31/5, paragraph 38*).

  Given that the pharma sector is particularly driven by innovation, competition authorities carefully scrutinise pharma mergers that have the potential to compromise R&D efforts and prevent the launch of innovative new drugs. The European Commission noted in 2019: "Reducing competition on innovation means that patients and healthcare systems would forego future benefits from innovative and affordable medicines. Harmful effects may include a loss of potentially better treatments, reduced future variety of medicines on the market, delayed access to medicines needed for the treatment of their conditions, and higher prices." (*Commission: Report on Competition enforcement in the pharmaceutical sector (2009-2017), page 42*.)

  Several Commission pharma merger investigations have focused on innovation effects, including in cases involving pipeline products in early stages of development. In *Novartis/GSK Oncology Business*, the transaction as originally notified would have resulted in Novartis acquiring two oncology drugs from GSK, which were marketed for the treatment of skin cancer and also being tested for the treatment of ovarian and other cancers. The Commission's investigation, which extended the analysis of pipeline products beyond those in the advanced stages of development (that is, Phase III clinical trials), found that the two GSK drugs competed directly with Novartis's own pipeline products which were

being tested for several cancer types. For each of the overlapping products, the Commission identified the risk that Novartis would have abandoned one of the parallel R&D programmes, as these would have been lengthy and costly.

In *Pfizer/Hospira*, the Commission was not only concerned that Pfizer's acquisition of Hospira's biosimilar product would lead to higher prices, but also that Pfizer might delay or discontinue the development of its own biosimilar version of infliximab, to the detriment of innovation and patient choice. While biosimilar drugs are clinically equivalent to the original biological product, they are not exact copies. Consequently, there is scope for a degree of product differentiation and non-price competition between different biosimilars of the same molecule. In the Commission's view, patients might lose out if an important biosimilar pipeline product were removed from the competitive landscape.

In *Johnson & Johnson/Actelion* (*Case M.8401, decision of 9 June 2017*), each of the merging parties was developing an innovative drug to treat insomnia. Although both projects were still at an early stage of development (in Phase II clinical trials), the Commission's investigation indicated that the two pipeline products were expected to have similar efficacy and safety profiles. There were also few competing third-party pipeline products. The Commission was concerned that the merger would adversely affect competition in innovation, since the merged entity was unlikely to have an incentive to continue both research projects after the merger.

Jurisdictional aspects of EU merger control: the Article 22 referral mechanism

Under Article 22 of the EUMR, a Member State may ask the European Commission to review a transaction that does not meet EU or national turnover-based thresholds but nevertheless:

- Affects trade between Member States.
- Threatens to significantly affect competition.

Introduced in 1990, the Article 22 referral mechanism was originally intended to deal with the situation of Member States which, at that time, had no merger control rules. With the progressive implementation of national merger control regimes in almost all Member States, the Commission had developed a practice of discouraging Article 22 referral requests from Member States that did not themselves have power to review the transaction in question under their own national rules.

In March 2021, however, the Commission published new guidance on the application of the Article 22 referral mechanism (see *Legal update, Commission Guidance on application of Article 22 of the Merger Regulation published in the Official Journal*##). The aim was to address a perceived "enforcement gap" relating to so-called "killer acquisitions" (acquisitions by large incumbents of nascent competitors that have the potential to play a significant competitive role in the market but do not yet generate

sufficient turnover to trigger any merger notification requirements). Concerns about killer acquisitions have focused in particular on the digital and pharma sectors in which innovation is central to competition. As noted above, innovators in the pharma sector may have strong competitive potential even before their R&D activities are complete.

The Article 22 guidance seeks to clarify the circumstances in which transactions that do not meet the turnover-based thresholds may be referred to the Commission for further review. It lists a number of factors which increase the likelihood of the Commission accepting a referral request. These include cases where the undertaking being acquired:

- Is a start-up or recent entrant with significant competitive potential (that is, it is yet to implement a business model generating significant revenues).
- Is an important innovator or is conducting potentially important research.
- Has access to significant competitive assets such as data or IP rights.
- Has little or no turnover but the value of consideration received by the sellers is particularly high.

The new guidance is particularly relevant to transactions in the pharma sector. The first case to be accepted by the Commission under the new guidance was *Illumina/GRAIL* (Case M.10188) (see *Illumina/GRAIL*). The proposed acquisition did not reach the notification thresholds set out in the EUMR, and it was not notified in any member state. However, amid concerns that the acquisition might reduce competition and innovation in the emerging market for the development and commercialisation of cancer detection tests based on sequencing technologies, France submitted an Article 22 referral request to the Commission. Subsequently, Belgium, Greece, Iceland, the Netherlands and Norway joined France's referral request. In July 2021, the Commission announced that it had decided to initiate an in-depth Phase II investigation to assess the proposed acquisition (see *Legal update, Commission opens Phase II investigation into proposed acquisition of GRAIL by Illumina*). Illumina appealed against the Commission's decision to accept jurisdiction (see *Legal update, Illumina appeals Commission decisions to accept Article 22 reference of Illumina/ GRAIL merger*). However, in a judgment of 13 July 2022, the General Court dismissed Illumina’s appeal, approving the position taken by the Commission in its March 2021 guidance paper. Illumina has appealed the General Court’s judgment to the Court of Justice (see *Legal update, Illumina appeals General Court judgment dismissing action against European Commission decision to accept Article 22 referral of its proposed acquisition of GRAIL*).

Illumina closed the transaction in August 2021, before the Commission had completed its investigation. The Commission responded by adopting interim measures in October 2021, requiring GRAIL to be kept separate from Illumina and to be run by an independent Hold Separate Manager, exclusively in the interest of GRAIL. On 24 January 2022, details were published in the Official Journal of the EU of an action brought by Illumina to appeal against the Commission's interim measures (see *Legal update, Illumina appeals Commission decision to adopt interim measures in relation to Illumina/ GRAIL merger*).

Subsequently, on 6 September 2022, the Commission adopted a decision prohibiting Illumina's acquisition of GRAIL, finding that Illumina would have the ability and incentive to engage in foreclosure strategies against GRAIL's rivals (see *Legal update, European Commission prohibits Illumina/ GRAIL merger*). This is the first time that the Commission has blocked a transaction falling below the EUMR and referring Member State notification thresholds. Illumina subsequently announced that it intended to appeal against the Commission's prohibition decision.

Remedies and appeals

Remedies

If a merger raises competition concerns and the parties do not propose suitable modifications, the transaction may be prohibited by the relevant competition authority. To avoid this, the parties can propose altering the transaction to remove the competition concerns. Such modifications are commonly referred to as remedies or commitments. If the proposed remedies appear fit for purpose, they are "market tested" with third parties (in particular, competitors and customers) to check that they would effectively eliminate the competition issues.

Remedies may be structural (for example, divestitures to remove competitive overlaps between the parties) or behavioural (such as commitments relating to the future conduct of the merged entity). However, both the European Commission and the CMA generally consider structural remedies, and particularly divestitures, to be preferable (see, in particular, section 3 of the *CMA's Guidance on Merger Remedies (CMA87)*). In recent years, there have been relatively few cases in which behavioural remedies alone have been accepted by the authorities. In the pharma sector, structural remedies often consist of the divestiture of entire product lines or marketing authorisations for problematic molecules, and may be accompanied by licences of IP rights and other technology transfers. Pipeline products are typically part of the remedies package in cases where innovation issues have been identified.

The design of remedies can often be complex in pharma merger cases. In *Novartis/GSK Oncology Business*, for example, the transaction was approved after Novartis committed to return one of the pipeline drugs to its owner and exclusive licensor (Array), and to divest the other pipeline drug to Array. Both commitments were conditional upon Array itself entering into a binding, Commission-approved agreement with a third party who could step into Novartis's shoes to further the development and commercialisation of the two drugs in the EEA. The Commission approved Pierre Fabre as a suitable partner of Array and subsequently monitored the implementation of the commitments.

In *Johnson & Johnson/Actelion*, Johnson & Johnson (J&J) offered remedies to ensure that the merger would not adversely affect the development of the two insomnia drug research programmes. The remedies consisted of two sets of complementary commitments. First, J&J committed not to influence any of the strategic decisions relating to the development of Actelion's insomnia pipeline product. To that end, J&J committed to limiting its investment to a capped minority shareholding in the company that would be developing this product and further committed not to receive any

information about the product. Second, J&J granted full control over the development of its own pipeline product to its partner, Minerva, and committed to continue financing the project, thereby ensuring that the programme would be developed independently.

Appeals

The EU's General Court has the power to review the legality of Commission decisions taken under the EUMR (see *Practice note, EU mergers and acquisitions: Appeals against merger decisions*). An appeal against a Commission merger decision can be brought not just by the merging parties, but also by third parties "directly and individually concerned" by the decision. Appeals to the General Court must be filed within two months and ten days of publication of the Commission decision or notification of that decision to the applicant. The Commission's decision will remain effective during the course of an appeal, unless the applicant can demonstrate to the Court that interim relief is appropriate. Appeals from the General Court to the EU's highest court, the Court of Justice, can be made on points of law only.

In the UK, any party aggrieved by a decision of the CMA or Secretary of State in relation to the merger review process may apply to the UK Competition Appeal Tribunal (CAT) to review that decision (see *Practice note, Review of merger and market investigation decisions under the Enterprise Act 2002*). Appeals must be filed within four weeks of the date on which the applicant was notified of the decision, or the date of the decision's publication if earlier. As with the EU procedure, filing an appeal does not have a suspensory effect on the decision to which the appeal relates.

Whenever the CAT considers an application to review a merger decision, it must apply the same principles as would be applied by a court on an application for judicial review. The CAT may either dismiss the application or quash the whole or part of the decision to which the application relates. If the CAT quashes the decision, it will refer the matter back to the original decision-maker with a direction to reconsider and make a new decision. Appeals from the CAT to the Court of Appeal can be made on points of law only, and require the permission of the CAT or the Court of Appeal. A further appeal on points of law can be made to the Supreme Court, subject to permission being granted by either the Court of Appeal or the Supreme Court itself.

Public interest considerations under the UK regime

The UK merger control regime also contains provisions which allow political involvement in certain limited categories of merger that raise public interest considerations (see *Practice note, Transactions and practices: UK Mergers and acquisitions: Secretary of State's powers to intervene in cases under the Enterprise Act*). In such cases, the Secretary of State (SoS) has the power to intervene and take over the role of decision-maker from the CMA. The areas in which the SoS may make a public interest intervention are limited by legislation, and currently cover national security and defence, the media sector, the stability of the UK financial system and (since the coronavirus pandemic) public health emergencies. The SoS may extend these categories, subject to parliamentary approval. Where a merger in one of these sectors has no adverse effect on competition but is deemed to be against the public interest, the

SoS may prohibit it or make clearance conditional on remedies that address the public interest concerns.

To date, public interest interventions by the SoS have been relatively rare. In July 2018, however, the UK government published a White Paper setting out proposals to enhance its ability to intervene in transactions on national security grounds, against a backdrop of increasing concern about the ability of the existing regime to protect the UK's national security effectively.

The *National Security and Investment Act 2021* (NSI Act) came into force on 4 January 2022 and gives the UK government enhanced powers to review and intervene in transactions that give rise to national security concerns. The introduction of the Act gives rise to the first mandatory notification regime in the UK for transactions in key sectors, including defence, synthetic biology "advanced materials" and artificial intelligence. For more information, see *Practice note, National Security and Investment Act 2021: overview*.

The NSI Act represents a significant extension to the previous national security provisions in the UK and imposes an obligation on companies operating in "sensitive sectors" to seek approval for certain types of transactions. It also enables the Department for Business, Energy and Industrial Strategy (BEIS) to "call in" transactions that may give rise to national security concerns if a so-called "trigger event" has taken place or is likely to take place in relation to a qualifying entity or asset. The UK government has, however, indicated that the new review process will remain targeted and proportionate, and that most transactions will be cleared without any intervention (see *BEIS and others: Press release: New and improved National Security and Investment Act set to be up and running*). The government has issued relatively few prohibition decisions under the NSI Act so far, but it is notable that the first such decision (which was issued in July 2022) was in respect of the proposed licensing of intellectual property of vision-sensing technology by the University of Manchester to Beijing Infinite Vision Technology Company. The government considered that the licence would create UK national security risks due to the dual-use application of the underlying technology, and the potential for the technology to be used to build defence or technological capabilities that could pose national security risk.

Looking ahead: proposals to amend the UK merger control regime

Several proposals to amend the UK's merger control regime have been put forward in recent years. In February 2019, the CMA published a letter from Lord Tyrie, Chair of the CMA, to the Secretary of State for Business, Energy and Industrial Strategy, outlining proposals for reform of the UK competition regime. Lord Tyrie's proposals included the introduction of mandatory merger filings for transactions above a certain threshold (to catch mergers typically reviewed by multiple international competition authorities), as well as the introduction of a standstill obligation for such transactions (see *Legal update, CMA letter to BEIS outlining proposals for reform of the competition and consumer protection regimes*). In November 2020, the CMA also published a report on the state of UK competition, aiming to provide a benchmark for further analysis and monitoring (see *CMA: The State of UK Competition Report (November 2020)*).

In March 2019, the UK Furman Report on "Unlocking Digital Competition" suggested that it may be appropriate to amend the jurisdictional reach of UK merger control by introducing an additional transaction-value threshold alongside the existing turnover and share of supply tests (see *HM Treasury: Unlocking digital competition, Report of the Digital Competition Expert Panel (13 March 2019)*). The report also proposed that the CMA should be allowed to use a "balance of harms" approach which takes into account the scale as well as the likelihood of harm in merger cases involving potential competition and harm to innovation (see *Legal update, Digital Competition Expert Panel publishes its report*).

In July 2021, the UK government published a consultation on its proposals for a new pro-competition regime for digital markets (see *Legal update, DCMS and BEIS consult on new pro-competition regime for digital markets*). The proposals are based on the recommendations set out in the Furman Report, as well as the CMA's final report of its market study into online platforms and advertising, and the Digital Markets Taskforce report to government published in December 2020.

On 6 May 2022, the UK government published its response to the consultation, setting out its policy decisions to inform legislation implementing the new digital markets regime (see *Legal update, Government response to consultation on new-pro competition regime for digital markets*). Taking into account feedback provided during the consultation process, the government decided to drop many of its most radical proposals for a bespoke merger control regime for firms with so-called strategic market status (SMS). However, if the government’s proposals come into effect, firms with SMS will be required to notify certain mergers to the CMA prior to their completion.

The government also intends to introduce new jurisdictional thresholds for UK merger control as part of its proposed reforms to the broader competition regime. In its April 2022 response to the consultation on "Reforming competition and consumer policy", the government stated that it wanted to "ensure that the merger control regime remains well-balanced by providing the CMA with jurisdiction to scrutinise mergers that are most likely to be harmful while also limiting costs and burden imposed on businesses engaging in economic activity that contributes to productivity, growth, and jobs across the UK" (see *Reforming competition and consumer policy: government response*). Specifically, the government has proposed:

- Amending the "turnover test" for establishing jurisdiction by increasing the turnover threshold for the acquired business from £70 million to £100 million.
- Creating an additional basis for establishing jurisdiction through a new "acquirer threshold", particularly to enable review of so-called killer acquisitions. Jurisdiction would be established where at least one of the merging firms has:
    - an existing share of supply of goods or services of 33% in the UK or a substantial part of the UK; and
    - a UK turnover of more than £350 million.

- Introducing a small merger safe harbour, which will exempt mergers from a review where each party's UK turnover is less than £10 million.

The government also stated that it will continue to monitor the operation of the existing share of supply test for establishing jurisdiction and may consider further proposals on how to reform it.

END OF DOCUMENT

RESOURCE HISTORY

General update following annual review.

General updates, including updates in relation to the Article 22 referral mechanism under the EU Merger Regulation, as well as the "Market definition for prescription drugs", "Public interest considerations under the UK regime" and "Looking ahead: proposals to amend the UK merger control regime" sections.

General update following annual review.

General updates, including those relating to Brexit, recent case and enforcement developments, UK government initiatives and the National Security and Investment Act 2021.