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EU Policy and Regulatory Newsletter

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ANTITRUST AND COMPETITION

The European Commission Approves Plan to Unwind a Completed Transaction in the Early Cancer Detection Sector

On 12 April 2024, the European Commission (Commission) approved the plan to unwind a transaction in the early cancer detection sector that was implemented before securing clearance and subsequently prohibited in 2022 by the Commission. While the transaction fell below the EU Merger Regulation (EUMR) turnover thresholds, the Commission asserted jurisdiction over the transaction based on a new interpretation under Article 22 of the EUMR, which grants the Commission the power to review transactions below the EU and national filing thresholds. According to the terms agreed with the Commission, the company is exploring several options to divest the target, which is expected to be finalized in the second quarter of 2024.

In 2021, following a referral request from six Member States, the Commission accepted to review the proposed acquisition of a US healthcare company developing cancer tests (Target) by a US genomics company (Buyer) (Transaction). The Commission relied on Article 22 of the EUMR to assert jurisdiction over this Transaction. In September 2022, the Commission prohibited the Transaction on the basis of concerns that it would have stifled innovation and reduced choice in the emerging market for blood-based early cancer detection tests. The Buyer and the Target had also prematurely completed the Transaction before securing the Commission's clearance, which prompted the Commission's gun-jumping investigation and imposition of a fine of €432 million on the Buyer. Moreover, in October 2023, the Commission adopted a decision to unwind the completed Transaction.

On 13 July 2022, the EU General Court confirmed the Commission's jurisdiction to review the Transaction under Article 22 of the EUMR. The Buyer and the Target appealed this decision. In March 2024, the Advocate General (AG) issued a nonbinding opinion recommending that both the EU General Court's judgment and the Commission's decision accepting jurisdiction under Article 22 should be set aside. The judgment of the Court of Justice of the European Union (CJEU) is expected by the end of 2024.

The Buyer has nevertheless decided to implement the Commission's restorative measures requiring the companies to unwind the Transaction. The restorative measures required the Buyer to submit a divestment plan for the disposal of the Target to the Commission for approval. On 12 April 2024, the Commission approved the plan to unwind the Transaction as submitted by the Buyer. The Commission found that the divestment plan, which included optionality between different divestment methods, met all the conditions set out in its decision imposing restorative measures. In particular, the Commission found that: (i) the plan grants the Target to restore

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independence at the same level as prior to the Transaction; (ii) the capability for the Target to operate as a viable and competitive business as it was before the Transaction; and (iii) the divestment options set out in the plan can be exercised in a timely manner within strict deadlines and with sufficient certainty, so that the pre-Transaction situation can be promptly restored.

The sale of the Target is expected to be finalized in the second quarter of 2024. The Commission's decision to unwind a Transaction remains exceptional as parties to merger transactions subject to EUMR do not close their transaction prior to clearance, given the automatic bar on closing that applies until the Commission issues a clearance decision. If the Commission's decision to assert jurisdiction is annulled by the CJEU, the Commission's prohibition decision over the Transaction, including the gun-jumping fine, will no longer have a valid legal basis and would be declared null and void by the General Court, where there are also pending appeals both against the prohibition decision and the gun-jumping fine. However, it remains to be seen whether the CJEU will uphold the Commission's jurisdiction under Article 22.

DIGITAL AFFAIRS

The Commission Identifies Shein as a Very Large Online Platform Under the Digital Services Act

On 26 April 2024, the Commission has formally identified the fashion online retailer Shein as a Very Large Online Platform (VLOP) under the Digital Services Act (DSA).

The Commission has also designated the following as VLOPs under the DSA: Alibaba, AliExpress, Amazon Store, Apple AppStore, Booking.com, Facebook, Google Maps, Google Play, Google Shopping, Instagram, LinkedIn, Pinterest, Pornhub, Snapchat, Stripchat, TikTok, X, XVideos, YouTube, and Zalando.

Shein has an average of more than 45 million monthly users in the European Union, which is above the DSA threshold for designation as a VLOP. Following its designation as a VLOP, Shein will have to conform to the stricter DSA rules linked to diligent surveillance of illegal products, improved consumer protection measures, and transparency and accountability from the end of August 2024 (four months after its notification). Under these rules, Shein will have to comply with the following obligations:

- Take measures to mitigate risks including the listing and sale of counterfeit goods, unsafe products, and items infringing intellectual property rights;
- Reinforce its internal processes, resources, testing, documentation, and oversight of all activities related to systemic risk detection;
- Diligently analyze the systemic risks inherent in the distribution of illegal content and products and in the design or functioning of its service and related systems;
- Implement an annual risk assessment that focuses specifically on any potential adverse effects on the health and safety of consumers, with particular emphasis on the physical and mental well-being of minor users;
- Design its platform in a way that mitigates and prevents risks to consumer safety and well-being;

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- Ensure that Shein's risk assessment and compliance with all DSA obligations are externally and independently assessed annually; and
- Publish repositories of all advertising displayed on its interface and provide access to public data to researchers.

Shein will also have to comply with the general obligation applicable to all online marketplaces, including those that are not a VLOP. This includes the following: to (i) develop their interface in a way that makes it easier for traders to comply with their legal obligations under EU legislations; (ii) guarantee the traceability of operators on their platforms; (iii) inform consumers of illegal purchases as soon as they are aware that the product is illegal; (iv) provide user-friendly mechanisms for users or entities to notify of illegal content; (v) give priority to processing notifications submitted; (vi) provide an internal complaints system for users to appeal content moderation decisions; and (vii) provide clear labelling of advertising on their interfaces.

The Commission, in cooperation with the Irish Digital Services Coordinator, will supervise Shein's conformity with the DSA, particularly in regard to measures to ensure consumer protection and to prevent the distribution of illegal products.

FINANCIAL AFFAIRS

The Council Discusses the Report on the Future of the Single Market and Potential Upcoming Initiatives in the Financial Services Area

On 17 and 18 April, EU heads of state and government discussed the report prepared by former Italian Prime Minister Enrico Letta on the future of the EU single market.

The document entitled “A single market to finance strategic goals” was commissioned in June 2023 by the European Council and the Commission to explore ideas boosting economic growth through deeper cross-border cooperation. It notably outlines several initiatives in the area of financial services. Importantly, the document calls for the creation of a “Savings and Investments Union,” built upon the incomplete Capital Markets Union. This new configuration would aim to further integrate and strengthen European financial markets and their ability to channel savings towards investments.

Furthermore, the report advocates for the introduction of a new long-term retail investment product by 2025, to stimulate retail investments, leveraging tax incentives from Member States and enhancing the pan-European personal pension product for broader market applicability. To address the lack of effective channels for retail savings into the real economy, the report proposes an EU-wide scheme enabling private savers to invest in alternative funds, alongside a new European scheme integrating national tax incentives and European Long-Term Investment Funds. Additionally, it advocates for contractual and institutional private-public partnerships to encourage further private investments, while ensuring a balanced regulatory framework.

Moreover, the report suggests establishing an EU stock exchange for deep tech companies, particularly in the quantum technology, artificial intelligence, and biotechnology sectors. The report also urges EU Member States and the Commission to enhance the supervisory framework in financial markets, aligning it with the mechanisms applicable in the banking sector. This includes empowering the European Securities and Markets Authority with

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increased supervisory responsibilities and revising the managing structure of the European Supervisory Authorities to improve their functionality.

The European Parliament Concludes Legislative Procedures of Several Financial Services Files

During the final plenary session of the current mandate that took place from 22 to 25 April, Members of the European Parliament (MEPs) wrapped up several legislative procedures in the area of financial services, while adopting the institutional negotiating mandate for other proposals.

Legislative Procedures Concluded

During the session, MEPs formally approved several texts, including:

Corporate Sustainability Due Diligence Directive

The directive will introduce mandatory due diligence requirements for both EU and non-EU companies. The Council of the European Union gave its final green light on 24 May: the directive will then be published in the Official Journal of the European Union (OJEU) and will enter into force 20 days later. Its provisions must be transposed into Member States' laws and will be applicable according to a staggered timeline, with the first group of companies to comply by circa 2027.

Solvency II Directive

The amendments to the directive incentivize insurers to invest in long-term capital for projects that contribute to the realization of the European Green Deal, while introducing a new macroprudential dimension to the resilience regime applicable to investors in this area.

Environmental, Social and Governance (ESG) Ratings Regulation

The regulation will govern activities of ESG rating providers and will enhance existing requirements for credit rating agencies when providing ESG scorings. It will introduce specific requirements to increase transparency on the methodologies applied, while requiring compliance with governance obligations. It will start to apply 18 months after publication in the OJEU.

European Market Infrastructure Regulation

The amendments to the regulation introduce further requirements for firms subject to clearing obligations, notably by requiring financial and nonfinancial counterparties to open an active account at an EU central counterparty.

Capital Requirements Directive and Capital Requirements Regulation

The amendments introduce several changes to banking supervision, adopted through the Basel III reforms. The reform aims to reduce uncertainty related to discrepancies in the risk-weight assignment, as well as unequal risk treatment between financial institutions. The revised regulation will be enforceable from 2025.

Adoption of European Parliament's Negotiating Mandate

MEPs have also endorsed the European Parliament's negotiating mandate for other proposals, to be negotiated with the Council of the European Union and the Commission in the new parliamentary term. This includes:

Payment Services Directive and Payment Services Regulation

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The two proposals will introduce new safeguards against payment fraud, enhance consumers' rights by providing full control on their payment data with open banking actors, and create a level playing field between banking and nonbanking entities. For the directive, the leading rapporteur is MEP Ondřej Kovařík (Czechia, Renew Europe), while for the regulation MEP Marek Belka (Poland, Progressive Alliance of Socialists and Democrats (S&D)) led the preparation of the final report.

Retail Investment Strategy

The strategy modifies several pieces of legislation to enhance retail investors' participation in financing operations. It would notably introduce a ban on inducements, while including a new test to ensure satisfaction of clients' best interest in investment activities. MEP Stéphanie Yon-Courtin (France, Renew Europe) is rapporteur for the proposal.

Benchmark Regulation

The proposal amends the regulation by streamlining administrative and regulatory burdens upon benchmark administrators, and introduces additional provisions on the conditions for benchmark administrators to use ESG factors in their methodologies. MEP Jonás Fernández (Spain, S&D) led the work on the file.

Bank Recovery and Resolution Directive (BRRD 3) and Single Resolution Mechanism Regulation (SRMR 3)

The amendments introduce a comprehensive reform of the Crisis Management and Deposit Insurance framework applicable to banks, specifically covering financial institutions' minimum requirements for own funds and eligible liabilities. MEP Luděk Niedermayer (Czechia, European People's Party) led the work on BRRD 3, while MEP Pedro Marques (Portugal, S&D) is leading rapporteur for SRMR 3.

SANCTIONS

The Directive Criminalizing Violation of EU Sanctions Enters Into Force

On 19 May 2024, the European Union's Directive on the definition of criminal offenses and penalties for the violation of Union restrictive measures (Directive Criminalizing Sanctions Violations) entered into force. As a result, since 20 May 2025, EU Member States are required to criminalize certain violations of EU sanctions set out below and impose corresponding maximum penalties in their national law.

Criminal Offenses

The following conduct must be considered a criminal offense if it is intentional and a violation of EU sanctions:

- Directly or indirectly making funds available to or for the benefit of a designated individual or entity;
- Failing to freeze funds belonging to, held, or controlled by a designated individual or entity;
- Violations of a travel ban;
- Engaging in prohibited transactions with third states;
- Trading and providing technical assistance or services relating to certain restricted goods;
- Providing certain restricted services;

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- Circumventing EU sanctions; and
- Breaching or failing to fulfil conditions under authorizations granted by competent authorities.

EU Member States may exempt certain conduct from criminal liability where the value of the funds, goods, services, transactions, or activities have a value of less than €10,000.

Penalties

Individuals committing a criminal offense shall be subject to a penalty of imprisonment for the most severe cases. Some offenses, such as certain failures to comply with reporting obligations are to be penalized by imprisonment of at least one year. Others will be subject to a maximum term of imprisonment of five years or more if Member States impose higher potential sentences, such as trading items included in the Common Military List of the European Union or dual-use items in breach of sanctions. In addition, EU Member States are required to provide for accessory criminal and noncriminal penalties that may include fines, withdrawals of permits and authorizations, and director disqualification.

Companies shall be held liable for a criminal offense where the offense was committed for their benefit by a person with a leading position within the company, such as a person with a power of representation and where a lack of supervision led to the commission of the criminal offense. Penalties to be provided for by the EU Member States must also include both criminal and noncriminal fines, and may include exclusion from access to public funding, disqualification from exercising business activities, withdrawal of permits and authorizations, closure of an establishment, judicial winding-up, and, where it is in the public interest, publication of the judicial decision. Fines must be proportionate to the gravity of the conduct and the circumstances of the company, but certain offenses must be subject to a penalty of not less than 5% of the total worldwide turnover or €40 million, whichever the relevant Member State chooses.

Cooperation with and disclosure of information to the relevant authority is to be considered as a mitigating factor.

AG Medina Clarified the EU Sanctions Prohibition to Provide Legal Advisory Services to Russian Entities

On 11 April 2024, AG Medina delivered her opinion in case C-109/23 “Jemerak.” The case required AG Medina to ascertain whether the authentication and execution of a contract of sale by a notary, in the context of a transfer of immovable property (apartment located in Berlin, Germany) owned by a legal person established in Russia, is prohibited under EU sanctions.

In general, EU sanctions (Article 5n (2) of Regulation No 833/2014) prohibit to provide, directly or indirectly, legal advisory services to either the government of Russia or to legal persons, entities, or bodies established in Russia (with certain exceptions, notably in relation to provision of services that are strictly necessary to ensure access to judicial, administrative, or arbitral proceedings).

According to Recital 19 of Regulation No 2022/1904 (which amended Regulation No 833/2014), the term “legal advisory services” is to be understood as covering (i) the provision of legal advice to customers in noncontentious matters, including commercial transactions, involving the application or interpretation of law; (ii) the participation with or on behalf of clients in commercial transactions, negotiations, and other dealings with third parties; and (iii) the preparation, execution, and verification of legal documents.

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Based on the Commission's nonbinding guidance of 21 December 2022, notarial services (such as authentication of contracts and other declarations directed at the performance of legal transactions) are covered by the prohibition under Article 5n (2) of Regulation No 833/2014.

However, in AG Medina's interpretation, for the legal tasks to be prohibited, they must incorporate the essential elements of the term “legal advisory services.” In particular, they must entail “advisory” character. As a result, the tasks of preparing, executing, and verifying legal documents must involve an element of legal advice if they are to be prohibited as “legal advisory services” within the meaning of Article 5n (2) of Regulation No 833/2014.

In AG Medina's view, the particular case of preparation and verification of the legal document by a notary in the context of a transfer of immovable property does not entail legal advisory services, i.e., providing advice to the parties in relation to how best to ensure that their wishes are met, in particular in contractual terms. This is because while a notary, during the authentication procedure, must inform the parties of their rights and obligations and of the effects flowing from the authentication of the document concerned, that task does not include providing advice to promote the specific interests of one or both of the parties.

Consequently, in AG Medina's opinion, the authentication by a notary of a contract of sale of immovable property is not prohibited, as long as, in the course of an authentication procedure, that notary does not provide any legal advice in relation to matters that are unrelated to authentication. AG Medina also noted that this reading is supported by the fact that if Article 5n (2) of Regulation No 833/2014 would be interpreted as prohibiting the authentication of a contract of sale of immovable property by a notary, which is typically an essential requirement for entry in the land registry, this would deprive Russian entities of any possibility to dispose of their assets and would place them in a position similar to entities subject to an asset freeze. However, none of the provisions of Regulation No 833/2014 sets out an express prohibition on all legal persons established in Russia from disposing of their immovable property assets.

Following the issuance of the AG's opinion (which is not binding, although followed by the Court of Justice in the vast majority of cases), the judges of the Court of Justice are now beginning their deliberations in this case. The binding judgment will be passed by the judges at a later date.

ENERGY

The European Parliament Adopts EU Methane Regulation

During its plenary session on 10 April 2024, the European Parliament adopted the new EU Methane Regulation. While the legislation still needs a formal approval by national energy ministers in the Council of the European Union later this month, it is the first EU attempt to curb energy sector methane emissions both domestically and in global supply chains. It sets requirement for the gas, oil, and coal industries to measure, monitor, report, and verify their methane emissions.

Requirements for methane emissions in the European Union include:

- Obligation for fossil fuel companies to report regularly to the competent authorities on quantification and measurements of methane emissions at source level, including for nonoperating assets;
- Obligation for oil and gas companies to carry out regular surveys of their equipment to detect and repair methane leaks on the EU territory within specific deadlines;

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- Ban of routine venting and flaring by the oil and gas sectors and restrictions for nonroutine venting;
- Obligation for fossil fuel companies to carry out an inventory of closed, inactive, plugged, and abandoned assets, such as wells and mines, to monitor their emissions and to adopt a plan to mitigate these emissions as soon as possible.

Requirements for methane emissions from imported fossil fuels include:

- As of January 2027, the regulation requires that new import contracts for oil, gas, and coal can only be concluded if the same monitoring, reporting, and verification obligations are applied by exporters as those that apply for EU producers. The regulation will set out a methane intensity methodology and maximum levels to be met for new contracts for oil, gas, and coal;
- The Commission will establish methane performance profiles of countries and companies to allow importers to make informed choices on their energy imports; and
- It will establish a methane transparency database where data on methane emissions reported by importers and EU operators will be made available to the public.

Once approved by EU governments, the new legislation will be published in the OJEU and enter into force.

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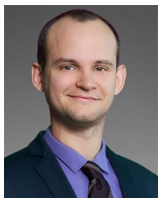
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