

# BRUSSELS REGULATORY BRIEF: APRIL

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## ANTITRUST AND COMPETITION

### A test case for a possible revision of the EU merger notification thresholds?

On 13 March 2017, it was announced that a United States ("**U.S.**") chipmaker will acquire an autonomous vehicle technology company based in Israel for approximately USD 15.3 billion. This transaction may provide an interesting case study for the lively debate on whether the EU merger control regime ("**EUMR**") needs to be reformed.

Currently, under the EUMR, a concentration has to be notified to the European Commission ("**Commission**") if the merging firms reach certain turnover thresholds, giving it a so-called "Union dimension". At national level, even though certain Member States (e.g. Spain, Portugal) also rely on the merging parties' market shares to assert jurisdiction over a transaction, the notification thresholds are generally based on the level of sales of the merging parties in a given country. Even if a transaction does not have a Union dimension, it may still be reviewed by the Commission thanks to the referral system.

However, the question has been raised whether the purely turnover-based thresholds enable the Commission to review all transactions which may have a significant impact on the internal market. The issue concerns mainly the pharmaceutical and digital sectors, where a big player may wish to acquire a small innovative company. Such companies often do not yet have a turnover high enough to satisfy the European Union ("**EU**") notification thresholds, but may have a "*competitive role, hold commercially valuable data, or have a considerable market potential for other reasons*".

For example, in 2014 the Commission was only able to review the acquisition of a consumer communications services provider by a U.S. company providing a social networking platform thanks to the referral system. As the EU merger filing thresholds were not met, the transaction would have otherwise escaped scrutiny at EU level.

In this context, the Commission launched in October 2016 a public consultation on "Evaluation of procedural and jurisdictional aspects of EU merger control", which ran until 13 January 2017. It asked, among other things, about the relevance of a complementary jurisdictional threshold based on the value of the transaction (i.e., a deal size threshold).

A similar debate is ongoing in Germany, where a revision of the merger control notification thresholds to take into account the value of a transaction is expected to enter into force during the second quarter of 2017.

It is interesting to see whether the recently announced acquisition will add useful elements to these debates. If the transaction does not meet the EU notification thresholds or even those of EU Member States, it may add to the arguments in favor of a revision of the EU jurisdictional thresholds to include a deal size threshold.

### **European Commission publishes proposal for a Directive to strengthen national competition authorities' antitrust enforcement powers**

On 22 March 2017, the Commission put forward a proposal for a Directive to empower the competition authorities of the Member States to be more effective enforcers and to ensure the proper functioning of the internal market ("**Directive**").

An initiative on this topic was expected since, in November 2015, the Commission launched a public consultation on the strengthening of national competition authorities' ("**NCA**s") enforcement powers. Also, back in September 2016, the EU Competition Commissioner ("**Competition Commissioner**") Margrethe Vestager noted that *"each authority has its own national traditions. So the best type of legislation may be a directive, not a regulation"*. Accordingly, the Commission had already hinted on the type of tool it would prefer to empower NCAs to be more effective enforcers of EU competition rules. (For further information, please see [here](#) our publication of November 2016). The Directive intends to tackle enforcement gaps and shortcomings identified in the NCAs' investigative powers by providing a "*minimum common toolkit*" for NCAs which would ensure a "*genuine common competition enforcement area in the Single Market*".

According to the Commission, the proposed new rules will ensure independence and impartiality of NCAs, as well as sufficient financial and human resources. They will also strengthen NCAs' investigative powers (e.g. right to search mobile phones, laptops and tablets), provide adequate tools to impose proportionate and deterrent sanctions (e.g. rules on parental liability and succession) and enforce the payment of fines, in particular when companies are not present on their territory, and make sure there is coordination of NCAs' leniency programs. The proposal also stresses the importance of safeguards for the respect of companies' fundamental rights. The Competition Commissioner noted in this regard that *"[...] with great power comes great responsibility. All competition authorities must use their authority appropriately, fully respecting companies' rights of defence. Companies have the right to know the case against them, and to have a chance to respond. Today's proposal therefore emphasises the fact that competition authorities must respect these rights, in line with the EU Charter of Fundamental Rights"*.

The Commission has sent its proposal to the European Parliament and the Council of the EU for adoption. Once adopted, Member States will need to transpose it to their national laws.

## **INTERNATIONAL TRADE**

### **Medicinal products: the EU and the U.S. mutually recognize GMP standards**

The EU and the U.S. have reached a sectoral agreement (the "**Agreement**") that will greatly ease the administrative burden when proving compliance with Pharmaceutical Good Manufacturing Practices ("**GMP**s") for certain medicinal products. In formal terms, the Agreement is an annex to the EU-U.S. Mutual Recognition Agreement ("**MRA**"), which was signed in 1998 to facilitate market access by reducing costs and time associated with obtaining product approvals. Even though the MRA already included provisions regarding GMPs for medicines, the Annex in question was never fully implemented: Article 1.3 of the Annex expressly stipulated that

*"the US and the EC [European Community, now EU] have agreed to revisit these concepts."* As such, in May 2014 the competent authorities from both blocs started reviving efforts to reach a revised agreement. The updated Agreement entered into force on 1 March 2017.

Under the current framework, generally speaking, (i) certain marketed finished pharmaceuticals for human use; (ii) certain marketed biological products; (iii) certain in-process material and intermediates; and (iv) active pharmaceutical ingredients or bulk drug substances will all benefit from the Agreement. For the time being, other medicinal products such as vaccines for human use, plasma derived pharmaceuticals, and veterinary products are not subject to the Agreement.

GMPs are a key element to quality assurance of medicinal products; ensuring they are produced and controlled pursuant to quality standards appropriate to their intended use. A lack of harmonization between GMP standards in different countries means companies wanting to export medicinal products must comply with differing requirements in the country of manufacture and the country of export.

The Agreement allows EU and U.S. regulators to rely on each other's inspections in their own territories. A Party to the Agreement shall recognize pharmaceutical inspections and accept official GMP documents issued by a recognized authority of the other Party for manufacturing facilities located in their territory. The recognized authorities are, for the U.S., the Food and Drug Administration ("**FDA**"), and for the EU, the competent national medicines and healthcare products authorities of each individual Member State of the EU. Practically, for the EU, this means it will no longer be necessary to verify whether medicinal products (that meet certain conditions) have been manufactured in conformity with GMPs prior to authorizing batch release of products onto the market. Similarly, for the U.S., it means the FDA will no longer have to conduct drug inspections in the EU. It will allow both blocs to concentrate their efforts and resources on other parts of the world where drug manufacturing for the EU or U.S. markets has greatly increased.

Further, the EU and the U.S. will be able to collaborate more closely in the event of product recalls, additional controls, suspension of distribution, or other problems concerning quality or noncompliance with GMPs. The Parties have agreed to have an alert system that permits authorities of the other Party to be made aware proactively in case of quality defect, recalls, counterfeit or falsified products, or other potential serious shortages.

Many provisions of the Agreement have already entered into force. Others will enter into force on 1 November 2017, when both the EU and the U.S. will have further assessed the other Party's recognized authorities.

In the current political context of EU-U.S. relations, after the Transatlantic Trade and Investment Partnership has been put on hold, to say the least, and when there may be transatlantic trade and regulatory tensions in the horizon, the importance of this Agreement goes beyond its material scope and content. The MRA has been welcomed as evidence that cooperation in technical matters with direct trade and economic impacts can exist, and it may act as a potential precedent for other specific deals in other matters.

### **European Parliament adopts the "Conflict Minerals Regulation"**

On Thursday 16 March, at its plenary meeting, the European Parliament ("**EP**") voted on the proposed Regulation setting up a Union system for supply chain due diligence self-certification of responsible importers of tin, tantalum and tungsten, their ores, and gold originating in conflict affected and high-risk areas ("**Conflict Minerals Regulation**"). The draft Regulation was approved by 558 votes to 17 with 45 abstentions.

The parliamentary vote constituted an important step after a long legislative process started in March 2014 with the presentation of the Commission's proposal ([here](#)) and marked by harsh interinstitutional negotiations. Those came to an end on 22 November 2016, when the EP and the Slovak Presidency of the Council of the EU ("Council") reached an informal agreement, which has just been ratified by the EP.

Once adopted by the Council, the deal will introduce for all, except smallest, European importers of raw conflict minerals mandatory due diligence checks on their suppliers. Importers of tin, tungsten, tantalum and gold and their ores from conflict-affected areas will need to abide by obligations concerning the management system, risk management, third-party verification and communication in accordance with the Organization for Economic Cooperation and Development's guidelines ([here](#)).

Companies not importing directly from conflict and high-risk areas, but using minerals in their manufacturing processes will be asked to report annually, on a voluntary basis, on the due diligence measures they have adopted and on their sourcing practices.

Due diligence obligations will apply from 1 January 2021 in order to allow Member States to put in place the necessary structures to ensure a smooth and EU wide implementation of the Regulation and companies to familiarize with the new obligations.

In parallel, on the other side of the Atlantic, the EU conflict minerals rules' counterpart, the so-called "Dodd-Frank Act" ("**Act**"), which was part of the Obama's 2010 financial reform package, has been questioned by Trump's administration and may be suspended.

In particular, section 1502 of the Act imposes on U.S. companies the obligation to track their supply chain to determine whether their minerals come from the Democratic Republic of Congo and surrounding countries and, if so, companies are required to perform due diligence reviews of their supply chain.

After the introduction of the Act in the U.S. legislation, big industrial groups lobbied to see section 1502 repealed or drastically revised. However, recently a coalition of 127 investors and investor groups representing over USD 4.8 trillion in assets under management have expressed their support for continuing the implementation of section 1502.

It now remains to be seen who President Trump will listen to.

## ECONOMIC AND FINANCIAL AFFAIRS

### G20 renews commitment to complete financial reforms

At a meeting in Baden-Baden, Germany, on 17 and 18 March 2017, G20 Finance Ministers and Central Bank Governors expressed their support to the finalisation and implementation of post-crisis reforms. One of the key objectives going forward is to monitor and address emerging risks and vulnerabilities, particularly those which have a systemic dimension or that are stemming from the interconnectedness with the shadow banking sector. The FSB committed to deliver guidance on central counterparty resolution planning as well as a series of reports, including on FinTech and on misconduct risk, by the July G20 Summit. In addition, the FSB is expected to release in July 2017 a framework for the assessment of the overall post-implementation effects of the financial reforms adopted in the wake of the 2008 crisis.

In the meanwhile, the finalisation of the so-called Basel III reforms within the Basel Committee on Banking Supervision ('**BCBS**') is being further delayed. Initially planned for 3 January 2017, the meeting of oversight body of BCBS has now been postponed several times. In a recent speech, Deutsche Bundesbank's Andreas Dombret indicated that the finalisation of the reform package was not to be expected in the short term as disagreements remain on key elements related to the treatment of banks' internal models. Moreover, despite the G20 renewed commitment to post-crisis reforms, uncertainty around the new US administration's stance on these issues appears to be a contributing factor to the delay in the finalisation of Basel III reforms.

### **European Commission issues action plan for consumer finance**

On 23 March 2017, the Commission released an [action plan](#) on consumer financial services, building on the results of its [green paper](#) public consultation, launched on 10 December 2015 in the framework of the Capital Markets Union ("**CMU**").

With this action plan, the European Commission sets out planned actions to increase consumer choice, competition and the cross-border supply of retail financial products in the EU single market. One of the main objectives of the action plan is to strengthen consumer trust in order to boost demand for cross-border retail financial services. Consequently, the European Commission proposes to address issues related to territorial restrictions, transparency and fees on cross-border service provision. In concrete terms, the action plan foresees lower charges on non-euro transactions, facilitated access to loans across borders and eased product switching. Among other elements, the plan also includes proposals to amend the Motor Insurance Directive and the close monitoring of transparent pricing in car rentals.

In addition, the consumer finance action plan lays the ground for the reduction of national barriers to cross-border provision of financial services and emphasises the potential of pan-European products, such as the European Personal Pension Product (PEPP) currently being developed by the European Commission with the help of the European Insurance and Occupational Pensions Authority (EIOPA). The European Commission also announced the publication of European creditworthiness assessments standards and principles by the second half of 2018.

Finally, the action plan proposes to create an adequate regulatory environment to foster the benefits of FinTech for consumers. This implies for example facilitating digital identity checks, via electronic identity schemes such as eIDAS, for bank-on boarding. Finally, the European Commission plans further work on identifying potential consumer risks and business opportunities to encourage online distance selling.

Overall, the European Commission considers that improving the cross-border market for retail financial services will benefit all consumers, including those who chose to remain with their domestic providers, by increasing the quality of services and lowering prices.

### **European Commission consults on FinTech regulatory framework**

On 23 March 2017, the European Commission launched a [public consultation](#) on FinTech, seeking feedback from stakeholders on how to foster a more competitive and innovative European financial sector. The consultation provides the opportunity for the European Commission to clarify its stance with regards to FinTech. It has outlined three core principles driving its regulatory approach to Fintech, namely (i) technological neutrality; (ii) proportionality; and (iii) market integrity.



Presenting the public consultation during a FinTech conference on 23 March 2017, the European Commission encouraged the industry as well as consumers to provide their feedback to help shape the future European FinTech framework. It is particularly interested in how FinTech can benefit consumers and boost the market for retail financial services. For the broader financial services sector, the European Commission considers that FinTech can contribute to reduce barriers to entry as well as operational costs, while increasing the efficiency of services and the competition in the market. At the same time, data protection and cybersecurity are key concerns.

## TAXATION

### G20 Finance Ministers and Central Bank Governors adopt a strong line on fair taxation

During the Baden-Baden meeting on 17 and 18 March 2017, G20 Finance Ministers and Central Bank Governors [reaffirmed](#) their commitment to implement the Base Erosion and Profit Shifting ('BEPS') package, under the leadership of the Organization for Economic Cooperation and Development ('OECD'). They encouraged all countries which have not yet done so to implement the OECD Common Reporting Standard ('CRS'), expected to be operational as of September 2017. They also mentioned that the G20 Summit in July 2017 will consider adopting defensive measures against jurisdictions that do not show sufficient progress in the implementation of the OECD standards.

Reflecting on current efforts across jurisdictions to address tax evasion, tax avoidance and money laundering, G20 Finance Ministers and Central Bank Governors stated that they will take steps to advance transparency of beneficial ownership and of legal arrangements. This will materialise in the effective implementation of international standards and in further cross-border exchange of information on beneficial ownership information.

### European Parliament adopts its position on transparency of beneficial ownership

The European Parliament adopted on 28 February 2017 its [report](#) on the [reform](#) of the Anti-Money Laundering Directive ('**AMLD 4**'), which was proposed by the European Commission on 5 July 2016. The existing [directive](#) is being revised in order to increase the transparency of financial transactions and corporate entities.

Based on the draft prepared by co-rapporteurs Judith Sargentini and Krišjānis Kariņš, the report calls to lower the threshold to be considered as a beneficial owner to 10% of the shares in the entity, as opposed to the 25% threshold initially proposed by the European Commission. The scope of powers granted to the European Commission is also widened by the report to cover exchange of information among member states, whistleblower protection and the assessment of the anti-money laundering frameworks of third countries.

Regarding publicity requirements, the report recommends that the beneficial ownership register should be made available to the public, either freely or on the basis of a limited fee to cover administrative costs. The risk assessment report that member states are required to address to the European Commission would also be made public in the form of a summary excluding confidential information.

Finally, the report adopted by the European Parliament calls on the European Commission to present by June 2017 a proposal to create a European financial intelligence unit to coordinate the fight against financial crime by means of exchanges of information, joint analyses and permanent coordination with the national units.

Trilogues are now ongoing between the European Parliament and the Council of the EU to agree on a common position.

### **PANA Committee of the European Parliament continues fact-finding missions**

Since February 2017, the European Parliament's Committee on money laundering, tax avoidance and tax evasion ('**PANA Committee**') has been conducting several fact-finding missions in various jurisdictions. The objective of these missions is to gather evidence and views by meeting with national governments, administrations and parliaments as well as with companies established in the country where the mission takes place.

Fact-finding missions took representatives of the PANA Committee to the United Kingdom on 9-10 February 2017, to Malta on 20 February 2017 and to Luxembourg on 2-3 March 2017. The PANA Committee also travelled to the United States ('**U.S.**'). From 21 to 24 March 2017, a PANA Committee delegation attended various meetings in Washington D.C. and in Delaware. The objective was to assess the state of play and perspectives for future EU-U.S cooperation in the fight against tax avoidance, tax evasion and money laundering. Transparency of beneficial ownership information and progress on OECD's BEPS were also on the agenda. This visit is particularly relevant as some European lawmakers have expressed concerns about the lack of tax transparency in the U.S.

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