MAY 2017

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Antitrust and Competition

New whistleblower tool introduced by the European Commission to strengthen its fight against cartels

On 16 March, the European Commission ("**Commission**") announced it had launched a new tool in its fight against cartels and other anti-competitive practices. The Commission unveiled a new whistleblowing tool, which would allow individuals to alert it of such practices but to retain their anonymity.

This new tool is complementary to the already existing leniency program which is one of the most successful means for detection of cartel activities by the Commission. Under the leniency program, companies can inform the Commission about a cartel in which they participated and apply for immunity or reduction of their fine. With the anonymous whistleblowing tool, the Commission is encouraging individuals to inform it of anti-competitive practices they may have knowledge of.

Under the new whistleblower tool, the Commission invites individuals to voluntarily provide information on facts, circumstances and individuals involved in an anti-competitive conduct, which are not publicly known. It also clarifies that this information can be related to either past, ongoing or planned anti-competitive conduct.

Whistleblowers can choose to reveal their identity. If not, the new tool provides the possibility to protect their anonymity, using an encrypted messaging system run by an external service provider. Individuals can provide information but they can also agree to two-way communication allowing the Commission to request clarifications or additional information.

Electricity capacity reserve plans in Germany under State aid scrutiny by the Commission

On 7 April, the Commission announced that it had started an in-depth State aid investigation into German plans for an electricity capacity reserve. Such measures, introduced by European Union ("**EU**") Member States, also called "capacity mechanisms", constitute financial support granted to electricity producers and consumers to safeguard security of electricity supply.

These EU Member States financial supports to electricity producers have to be assessed on the basis of State aid rules. Under that regime - which is peculiar to the EU only and does not exist in other regimes globally - any form of advantage (e.g. financial support, better terms and conditions) conferred on a selective basis to companies by public authorities of the Member States is illegal unless it has been approved by the Commission. In 2014 the Commission adopted guidelines on State aid for environmental protection and energy, which provide specific compatibility criteria for the assessment of capacity mechanisms.

Because of its current transition to a low carbon, environmentally sustainable energy supply, Germany's planned capacity reserve measure is intended as a safeguard against unforeseen developments in case demand cannot be met by the electricity market. However, the Commission has identified a number of initial concerns, which it will assess with regard to the compatibility with State aid rules.

In particular, the Commission has raised concerns about the need of the reserve and about the fact that the reserve may continue to exist even if it will no longer be needed in the future. In addition, according to the Commission, the criteria for participation in the reserve may not be sufficiently open for demand response operators and they also exclude foreign capacity providers. Finally, the initial view of the Commission is that all possible market reforms may not have been carried out by Germany so as to ensure security of supply without State intervention - which would be illegal under State aid rules if the German measures were not previously authorized by the Commission.

International Trade

Council formally adopts Directive on shareholders' rights in EU companies

On 3 April 2017, the Council of the European Union adopted a Directive amending the current Shareholders' Rights Directive 2007/36/EC ("**SRD**"), which is meant to strengthen shareholders' engagement in European listed companies. The revision of the SRD is part of the Commission's 2012 Action Plan on company law and corporate governance.

The revised Shareholders' Rights Directive ("**SRD II**") is the result of certain specific shortcomings in corporate governance of European listed companies that were exposed by the financial crisis and created strong social and political criticism. Indeed, in many cases, shareholders supported excessive short-term risk taking by unscrupulous managers, and in many cases it appeared evident that high, often excessive directors' pay was not justified by performance (or even rather the opposite). The SRD II tries to provide a response to this situation, without going as far as some voices had asked for, in terms that may have resulted in excessive interference with private companies' internal governance. The text's main official goal is to contribute to the sustainability of EU companies, thus resulting in growth and job creation, through shareholder long-term engagement and increased investment and voting transparency.

The main changes outlined in the SRD II are the following:

1. *Identification of shareholders and facilitation of the exercise of shareholders' rights*
The SRD II will allow companies to identify their shareholders and to obtain information regarding shareholder identity from intermediaries (i.e. an investment firm, a credit institution, a central securities depository, that provide services of safekeeping of shares, administration of shares or maintenance of securities accounts on behalf of shareholders or other persons). The purpose of this disclosure obligation is to facilitate the exercise of shareholders' rights and to increase shareholder participation in and voting at general meetings. Intermediaries will also have to provide to shareholders all information from the company that will allow the appropriate exercise of their rights.

2. *Control over directors' remuneration*
Under the SRD II, shareholders will have the right to vote on the remuneration policy of the company's directors. This remuneration policy must contribute to the company's business strategy, long-term interests and sustainability. Also, the directors' performance must be assessed taking into account both financial and non-financial performance criteria.

3. *Transparency for institutional investors, asset managers and proxy advisors*
The SRD II requires investors to either develop and publicly disclose a policy on shareholder engagement, or to give a clear and reasonable explanation as to why they have chosen not to do so (the so-called 'comply or explain' approach). This engagement policy must include the conduct of dialogue with the company, the exercise of voting rights, and the management of actual or potential conflicts of interest. The policy must also describe how the investor or asset manager monitors the company invested in.

   Proxy advisors - who analyze corporate disclosure and other information of listed companies with a view to informing investors' voting decisions by providing research, advice or voting recommendations that relate to the exercise of voting rights - are subject to similar transparency rules, in view of the important role they play. They are required to adopt a code of conduct, as a guarantee of the reliability and quality of their recommendations on how to vote in general meetings of listed companies.

4. *Related party transactions*
The SRD II provides that transactions with parties related to the company ("related party transactions") should be approved by the shareholders, the management or a supervisory body, to provide adequate protection for the interests of the company.

   Also, companies will have to publicly announce material transactions at the time of the conclusion of the transaction in order to assess the fairness and accuracy of the transaction from a shareholder's perspective.

The SRD II will be published in the Official Journal of the EU. The Directive will enter into force on the twentieth day following that of its publication, and Member States will then have up to two years to transpose the Directive into national law.

The European Parliament adopts Medical Devices and In-Vitro Medical Devices Regulations

On 5 April, the European Parliament ("**Parliament**") adopted the Package on medical devices. It consists of two Regulations: the Regulation on medical devices and the Regulation on *in vitro* diagnostic medical devices. The final texts are the result of a long negotiation process started in 2012, after the Commission's proposals were presented, and of a wide expert consultation, which resulted in an agreement among Member States' health ministers on 5 October 2015.

The overhaul revises the existing legislative framework on safety and performance of medical devices dating back to the '90s, with the purpose of improving the market oversight framework, ensuring a harmonized regime on medical and *in vitro* diagnostic devices and that these reflect technological and scientific progress/development. The Regulations will apply to all medical devices, *in vitro* medical devices and their accessories, as well as to certain aesthetic products, previously unregulated.

The reform introduces stricter controls on clinical trials and on notified bodies. For high-risk devices, notified bodies will be required to consult a new Medical Device Coordination Group ("**MDCG**") before their commercialization. These panels, composed by Member States experts and headed by the Commission, will release non-binding scientific opinions on the assessment of the medical devices. In case notified bodies choose not to follow them, they will need to provide a justification for their decisions, which will be published on a EU Database on medical devices, to be set up by the Commission by 2020 and providing a picture of the products available in the European market.

Furthermore, pre-market conformity assessment procedures will be carried out in line with a new risk classification system, which organizes medical devices and *in vitro* medical devices into four categories in accordance with international guidelines.

The Regulations impose on manufacturers the obligations to collect clinical evidence of the performance of devices available on the market and to adopt a sound financial mechanism able to compensate patients receiving defective products. These financial compensation systems shall be proportionate to the type of device, its risk class and the size of the company.

Concerning the registration of devices and operators, currently required in all Member States where products are commercialized, it will need to be done only once at the EU level, significantly reducing the red tape.

Following the entering into force of the Regulations, certificates issued under the current Directives will remain valid for an additional period of time, which is of three years for the Regulation on medical devices and of five years for the Regulation on *in vitro* diagnostic medical devices.

Economic and Financial Affairs

European Commission conducts mid-term review of the Capital Markets Union

Following a public consultation to gather stakeholders' views on mid-term achievements and challenges for the Capital Markets Union ("**CMU**"), the Commission organised a public hearing to discuss further steps.

Discussing in particular the development of sustainable finance, European Commissioner Vice-President Valdis Dombrovskis mentioned that the Commission's High Level Expert Group will publish a first report by summer 2017 and a final report by the end of the year. Its approach will encompass social and environmental elements.

The public hearing also reflected on the growing potential of FinTech to improve the efficiency of EU capital markets with regard to accessibility, operational costs and innovation.

In addition, the mid-term review of CMU is being impacted by the upcoming exit of the UK from the EU ("**Brexit**"). As London currently hosts the largest and deepest capital market in the EU, the Commission considers Brexit as an opportunity to reshape European capital markets to the benefit of EU citizens.

European Commission consults on the supervisory architecture in a Brexit context

On 21 March 2017, the Commission launched a public consultation on the future of the European Supervisory Authorities ("**ESAs**"). The overall objective is to strenghten the coherence of the supervisory framework in order to boost the development of capital markets, given that Brexit will redefine the European financial landscape.

The consultation paper covers the three existing ESAs, namely the European Securities and Markets Authority ("**ESMA**"), the European Insurance and Occupational Pensions Authority ("**EIOPA**"), and the European Banking Authority ("**EBA**") and aims at identifying areas where the ESAs' efficiency and effectiveness can be improved. It suggests potential budget increases for the ESAs, along with an overhaul of their powers and governance arrangements.

The consultation paper also raises the question of a potential merger of EIOPA and EBA, which would be associated with stronger consumer protection powers for ESMA. Simultaneously, it underlines the need for strong and central financial supervision in light of capital markets partly relocating from the United Kingdom to other jurisdictions as a result of Brexit.

The public consultation runs until 16 May 2017.

FSB proposed framework to assess post-crisis reforms

On 11 April 2017, the Financial Stability Board ("FSB") published a consultation paper outlining a proposed framework for post-implementation evaluation of the effects of the G20 financial regulatory reforms.

The FSB underlines the importance of assessing the efficiency of the comprehensive post-crisis program which was launched by the G20 in 2009 to increase the resilience of the global financial system. Importantly, the FSB also aims at identifying potential unintended consequences of post-crisis reforms.

The proposed framework suggests that the evaluation process should facilitate appropriate consultation and collaboration between all bodies involved, including public consultations on evaluations prior to their final publication. The objective is to offer all stakeholders the opportunity to comment on each evaluation. The FSB also emphasizes that the exercise should be data-driven and include an assessment of social costs and benefits.

Comments can be submitted until 11 May 2017. The FSB is due to publish its final report ahead of the G20 Leaders' Summit in July 2017.

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