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The April issue of the Brussels Regulatory Brief includes the following topics:

- **Defence and Security**

Establishment of the European Defence Fund. *On 20 February 2019, the European Parliament and the Council of the EU reached a partial political agreement on the European Defence Fund aiming to establish an innovative and competitive defence industrial base and contribute to the EU's strategic economy, autonomy, technological leadership and cooperation in defence.*

- **Antitrust and Competition**

European Commission accepts commitments and ends a 5-year investigation in pay-TV services. *The Commission have made commitments to remove territorial restrictions from licensing agreements offered by five US film studios and a UK pay-TV broadcaster legally binding.*

European Commission publishes Report on Competition Enforcement in the Pharmaceutical Sector (2009-2017). *The Report on Competition Enforcement in the Pharmaceutical Sector, which was published on 28 January 2019, provides an overview of competition enforcement activities in the pharmaceutical sector under Article 101 and 102 TFEU. It also reviews how the Commission applied merger control rules to ensure the preservation of R&D projects and the development of affordable and innovative medicines and treatments.*

- **Economic and Financial Affairs**

EU co-legislators reached agreement on the overhaul of financial supervisory architecture. *On 21 March 2019, the European Parliament and the Council reached a political deal on the review of the EU financial supervisory system.*

EU finance ministers reject digital advertising tax. *The Council of the EU failed to reach unanimity on an EU short term solution to the taxation of digital services.*

Defence and Security

Establishment of the European Defence Fund

On 20 February 2019, the European Parliament and the Council of the EU reached a partial political agreement on the European Defence Fund (the “EDF”). The EDF, which is expected to be funded with €13 billion, aims to establish an innovative and competitive defence industrial base and contribute to the EU’s strategic economy, autonomy, technological leadership and cooperation in defence.

The European Commission presented the EDF proposal in June 2018, as part of its EU long term budget (the multiannual financial framework, the “MFF”) for the years 2021-2027, in an effort to tackle increasing instability and cross border threats to security. The Commission expects the EDF to help the EU benefit from cutting-edge, interoperable defence technology and equipment in novel areas such as artificial intelligence, encrypted software, drone technology and satellite communication.

In particular, the co-legislators agreed on a number of key elements, including: (i) the provision of support all along the industrial lifecycle, from research to prototype development up to certification; (ii) the financing of collaborative research projects mainly through grants; (iii) the provision of higher financing rates for projects with cross-border participation of the many SMEs and mid-caps in the EU defence supply chain; (iv) the definition of projects in line with the defence priorities agreed by Member States in the framework of the Common Foreign and Security Policy, although regional and international priorities, such as those agreed in the framework of NATO, will also be taken into account; (v) at least 4% and up to 8% of the budget will be allocated to disruptive, high-risk innovation; (vi) eligibility for funding will only be granted to collaborative projects, involving at least three entities from at least three Member States or associated countries; (vii) the principle according to which only entities established in the EU or in associated countries and not controlled by third countries or their legal entities will be eligible for funding, while entities based outside the EU will only be entitled to participate in cooperative projects, but not to autonomously receive EU funding.

Following the announcement of the creation of the EDF by the President of the European Commission during his State of the Union speech in November 2016, the Commission initiated two research projects: Ocean2020, which brings together 42 partners from 15 EU countries to integrate drones and unmanned submarines into fleet operations; and the European Defence Industrial Development Programme to co-finance joint industrial projects in the field of defence. As mentioned, on the basis of these two ‘pilot’ programmes, the EDF is planned to receive €13 billion in the framework of the 2021-2027 MFF to cover both the research and capability strands. Of this budget, €4.1 billion will cover collaborative defence research, where up to 100% funding is possible, while €8.9 billion will complement Member States’ investment, by co-financing the costs for prototype development (up to 20% of costs) and the ensuring certification and testing requirements (up to 80% of costs).

The provisional agreement, however, does not include the final overall EU budget, as the 2021-2027 MFF still needs to be approved by the Parliament in autumn 2019. This agreement, resulting from the EU inter-institutional negotiations, is now subject to formal approval by the Parliament and Council.

Antitrust and Competition

European Commission accepts commitments and ends a 5-year investigation in pay-TV services.

On 7 March 2019, the European Commission announced it made legally binding commitments offered by five US film studios and a UK pay-TV broadcaster.

Under EU competition law, the commitment procedure allows companies in the context of a competition investigation to offer commitments to the Commission. If the Commission considers that these commitments address its competition concerns, it makes them legally binding, does not reach a conclusion on the infringement and does not impose fines. A breach of binding commitments may result in fines up to 10% of the company’s global turnover in the last financial year.

When opening its investigation in July 2015, the Commission noted that clauses between six US film studios and a UK pay-TV broadcaster raised competition concerns. According to the contested clauses, the broadcaster was required to refuse unsolicited subscription requests for its online and satellite content from consumers outside its licensed territory (the UK and Ireland) and the studios were required to impose the same requirement on other pay-TV broadcasters in the EU. Such restrictions amounted to a restriction of “passive sales”, i.e. sales made in response to unsolicited requests from individual customers including delivery of goods or services to such customers. According to EU competition law, online sales and the use of the Internet fall within the category of passive sales. The Commission had preliminarily found that such restrictions of passive sales eliminate cross-border competition between broadcasters and create barriers between national markets.

The Commission already accepted, in July 2016, commitments from one of the six studios to remove the litigious clauses from its future licensing agreements in the EU and not to implement such clauses in existing licensing agreements. A French pay-TV broadcaster challenged this Commission's decision before the General Court of the EU (General Court), considering that removing territorial restrictions from licensing agreements would undermine the way films are distributed and financed in Europe. Indeed, the broadcaster noted that such clauses are linked to the fact that content is licensed on a country-by-country basis and that licensing fees are used to fund films at national level. The General Court, in a judgement from 12 December 2018 and currently under appeal, rejected all arguments raised, considering that such clauses were hardcore restrictions of competition, i.e. restrictions that are likely to produce negative effects on the market and are unlikely to be justified on grounds of efficiency or any other pro-competitive effect. In particular, the General Court found that restricting cross-border competition could not be justified by the fact that licensing agreements relate to content covered by copyrights and that licensing fees were artificially high, running counter to the creation of a single market.

Another of the six studios concerned submitted similar commitments to the Commission in November 2018. The four remaining studios subject to the Commission's investigation submitted their commitments after the General Court's ruling.

According to the commitments accepted today, the five studios will not introduce territorial restriction clauses in future agreements and will not seek to enforce or bring legal actions for the violation of the existing litigious clauses. Similarly, the UK pay TV-broadcaster will not introduce such clauses in future agreements and will not seek to enforce such clauses in existing agreements with the six studios concerned. This set of commitments will allow EU consumers located outside a particular licensed territory to access satellite and online content provided for this territory.

The companies referred and any person directly and individually concerned by the decision have two months from the date of its adoption to appeal to the General Court.

European Commission publishes Report on Competition Enforcement in the Pharmaceutical Sector (2009-2017)

The Report on Competition Enforcement in the Pharmaceutical Sector, which was published on 28 January 2019, provides an overview of competition enforcement activities in the pharmaceutical sector under Article 101 and 102 TFEU. It also reviews how the European Commission applied merger control rules to ensure the preservation of R&D projects and the development of affordable and innovative medicines and treatments.

[The Report on Competition Enforcement in the Pharmaceutical Sector 2009-2017](#) ("the Report") follows the Pharmaceutical Sector Inquiry report (2000-2007) published by the Commission in 2009. This Report was spurred by the Council and the European Parliament's concerns regarding patient's access to affordable and innovative essential medicines due to the level of prices and limited bargaining power of national governments towards pharmaceutical companies.

Over the period 2009-2017, the Commission and 13 National Competition Authorities ("NCAs") adopted [29 decisions](#) finding either an infringement or accepting commitments in cases involving pharmaceuticals for human use. The most widespread type of competition issues in these decisions were abuse of dominance and restrictive practices such as pay-for-delay, bid rigging and clauses prohibiting distributors from promoting and selling competing manufacturers products. In 24 out of these 29 decisions, an EU law infringement was found leading to a prohibition decision, and in 21 of these cases fines were imposed for more than €1 billion in total.

As regards mergers in the pharmaceutical sector, over 80 merger filings were analyzed in the period concerned, of which 19 were deemed problematic from a competition standpoint due to the risk of price increase or the risk of depriving the patients of medicinal products amongst others. The Report finds that appropriate remedies proposed by the merging pharmaceutical companies enabled the preservation of R&D projects and the development of new medicines.

The Report highlights how competition law enforcement contributes to affordable medicines, in particular by ensuring the entrance of generics in the market. The Commission conducted a study showing that prices of innovator medicinal products drop on average by 40% after generic entry. Notably, the Commission and the General Court of the EU (General Court) issued infringement decisions concerning pay-for-delay practices in cases T-472/13 and T-691/14. In these decisions, pay-for-delay practices were deemed to be akin to market sharing agreements infringing Article 101 TFEU. In the cases where the originator company held a dominant position, it was also found that the practices aiming at delaying generic entry infringed Article 102 TFEU. The Court of Justice, in case C-457/10 P, also found an abuse of dominant position in a case where regulatory procedures were misused as part of a commercial strategy to launch a follow-on product, which amounted to mislead public authorities.

Unfair pricing practices amounting to an abuse of a dominant position were also reviewed in the Report. In the timeframe at hand, NCAs pursued a number of unfair pricing matters concerning off-patent medicines, notably the Italian and UK NCAs. Other practices capable of inflating the prices of pharmaceuticals, such as coordination between competitors and practices of excluding competitors or limiting their ability to compete, have been under the scrutiny of NCAs in particular in Italy, Spain and Cyprus.

Economic and Financial Affairs

EU co-legislators reached agreement on the overhaul of financial supervisory architecture

On 21 March 2019, the Council of the EU and the European Parliament (“co-legislators”) reached a [provisional political agreement](#) on a package of proposals reviewing the functioning of the current European system of financial supervision (“ESFS”). The political deal marks a major milestone in the financial affairs agenda under the current legislative term.

Also referred to as the “ESAs review”, the package includes [amendments to the founding regulations](#) of the three European Supervisory Authorities, the “ESAs” i.e. European Banking Authority (“EBA”), European Securities and Markets Authority (“ESMA”) and European Insurance and Occupational Pensions Authority (“EIOPA”) as well as [targeted changes](#) to the functioning of the EU’s macroprudential body, the European Systemic Risk Board (“ESRB”).

The amendments reinforce the ESAs’ competences in the oversight of EU financial markets amid numerous changes in financial services regulation, efforts to build a Capital Markets Union (“CMU”), and Brexit looming. Under the new rules, the ESAs will also have to consider new developments in FinTech or sustainable finance in their supervisory work and foster a common EU supervisory culture.

The reform equips ESMA with direct supervisory powers over third country and critical benchmark administrators, as well as over data reporting service providers, with the exception of small local providers. The review clauses of the new law point to a possibility of direct supervision of third country trading venues and central securities depositories by ESMA in the future. The Commission is mandated to explore the merits of transferring these powers to ESMA two years after the adoption of the new rules.

The EBA’s role has been particularly reinforced as regards tackling money laundering, which was previously distributed among the three ESAs. A stronger EBA should help ensuring an early identification of weaknesses and a swift supervisory action when anti-money laundering rules are breached at national level. Among other tasks, the EBA will be collecting information from national competent authorities (“NCAs”), develop common standards, perform risk assessments and facilitate cooperation with non-EU countries on cross-border money laundering cases.

The co-legislators decided to maintain the existing funding system for the ESAs’, which is based partly on the EU budget and partly on NCAs’ budgets, but added the possibility of a voluntary contribution from EU Member States or observers. As for the ESAs’ governance, the Member States in the Council managed to preserve a key role for their national authorities, maintaining that the decisions have to be taken by the ESAs’ Board of Supervisors, which is composed of the heads of NCAs. The ESAs’ toolkit for ensuring supervisory convergence in the EU has been broadened to include the possibility to establish coordination groups at EU level. From a consumer protection perspective, the ESAs’ product intervention powers have also been reinforced.

The texts have already been formally endorsed by the Council’s Permanent Representative Committee (“COREPER II”) and are expected to be adopted by the Parliament’s plenary on 17 April.

EU finance ministers reject digital advertising tax

On 12 March 2019, EU finance ministers took stock of progress reached in the negotiations on the short term solution to the taxation of digital services at the meeting of the Economic and Financial Affairs Council (“ECOFIN”).

Following the December’s ECOFIN meeting and based on a proposal by France and Germany, the original text of the digital services tax (“DST”) was reduced in scope, leaving online platforms as well the transmission of data out of scope and targeting only digital advertising instead (i.e. the proposal was renamed into digital advertising tax or “DAT”).

The Romanian Presidency of the Council was originally aiming to reach a [political agreement](#) on its compromise proposal on the DAT at the meeting on 12 March. The text was rejected, despite a large majority of Member States supporting the proposal or willing to concede based on the proposed deferred application date (i.e. January 2022) and a sunset clause linked to a possible future Organisation for Economic Co-operation and Development (“OECD”) approach on digital taxation.

In particular, Denmark, Sweden, Estonia and Ireland reiterated their opposition to the EU interim solution based on revenue taxation, arguing that it would fundamentally alter the international tax system and ultimately affect global growth, exports, investments, as well as research and development. Numerous ministers underlined that even if the

compromise DAT had been significantly watered down, it would have been better than 28 unilateral measures and Europe sending a divided message. Austrian finance minister Hartwig Löger noted that during the Austrian Council Presidency, U.S. counterparts and global firms called for a unified and clear outcome supported by all Member States. France and Germany called on others to cooperate closely at OECD level and to support their proposal on a minimum tax rate.

The Romanian Presidency concluded the discussion suggesting a two-track approach going forward. Work on an international digital tax solution by 2020 would continue at the OECD level, along with the examination of the Commission's long term proposal on the digital significant presence at the EU level. In case of delays in the adoption of the OECD solution, the Council would revert to the negotiations of the DST/DAT and introduce an EU interim tax regime on digital services.

The Commissioner for Economic and Financial Affairs, Taxation and Customs, Pierre Moscovici, added that the Commission does not intend to withdraw its proposal, arguing that it helps to speed up international discussions. Following a public consultation and a hearing, the OECD is expected to provide an update on its work to the G20 finance ministers in June 2019.

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