COVID-19 KEY EU DEVELOPMENTS
POLICY & REGULATORY UPDATE

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This regular alert covers key regulatory EU developments related to the COVID-19 situation. It does not purport to provide an exhaustive overview of developments and contains no analysis or opinion.

LATEST KEY DEVELOPMENTS

Competition & State Aid

- European Commission releases State of the Union 2022 report
- European Commission endorses final Member State recovery and resilience plan
- Commission approves up to €5.2 billion of public support for second IPCEI in hydrogen value chain
- European Commission approves further schemes under Ukraine Temporary Crisis Framework
- European Commission approves further schemes under COVID Temporary Crisis Framework

Trade / Export Controls

- European Commission publishes 40th Annual Report on EU's Anti-Dumping, Anti-Subsidy and Safeguard activities in 2021
- European Commission publishes proposed Regulation establishing a Single Market Emergency Instrument
- G7 Trade Ministers Meeting

Medicines and Medical Devices

- European Commission proposes Council Recommendation for a new approach on cancer screening
- HaDEA issues call for proposals for €5 million project to support dialogue on public procurement in health sector and crises preparedness

Cybersecurity, Privacy & Data Protection

- European Commission proposes European Media Freedom Act
- European Commission proposes Cyber Resilience Act

COMPETITION & STATE AID

State Aid

European Commission releases State of the Union 2022 report (see here)

On 8 September 2022, the Commission published its annual State of the Union report, presenting an overview of its work and achievements over the past year (Report).

The Report states that the historic COVID-19 pandemic and Russia's war against Ukraine have confirmed that the European Commission, under President Ursula von der Leyen, was right to launch a new and ambitious course in December 2019 to build a greener, digital and socially just Europe. The pandemic lockdowns vastly accelerated the digital transition, and the Kremlin's energy blackmail is further driving the need to free the EU from dependency on Russian fossil fuels, according to the Report.

On dealing with the pandemic and Ukraine crises, the Report highlights, in particular:

- State aid has served as an important part of the Commission's economic response to both crises (*see below for further details on these State aid measures*):
  - Since the COVID-19 pandemic's emergence, the Commission has adopted more than 1,430 State aid decisions, approving nearly 1,010 national measures for an estimated total amount approved of around EUR 3.2 trillion.
  - On Ukraine, the Commission adopted a State Aid Temporary Crisis Framework in March 2022 to enable Member States to support the economy in the context of the Russian invasion, while preserving competition. The Report indicated that the Commission had adopted 89 decisions, for an estimated total approved amount of nearly EUR 430 billion.
- NextGenerationEU, the EU's historic recovery fund for rebounding from the COVID-19 crisis (and now also the energy crisis), is worth over EUR 800 billion and reaches a total of over EUR 2 trillion when combined with the EU's long-term budget towards 2027. Notably:
  - The Recovery and Resilience Facility (RRF), to recall, is the key component of NextGenerationEU. Member State recovery plans have set out the reforms and public investment projects foreseen for implementation with the RRF, which will provide up to €672.5 billion to finance reforms and investments (i.e., grants totaling €312.5 billion and €360 billion in loans). These national recovery plans must comply with State aid rules (*see below for further details on the RRF*). Thus far, over €100 billion has been disbursed to Member States under the RRF, or around 20% of allocated RRF funds.
  - Following Russia's invasion of Ukraine, the RRF is to serve as one of the main delivery tools to make the EU independent from Russian fossil fuels well before 2030 under the REPowerEU plan (see here and here). REPowerEU comes with nearly €300 billion

	in financial support, including €225 billion in loans available to Member States from NextGenerationEU (*see also Jones Day White Paper, REPowerEU: A New Energy Landscape for Europe, July 2022*). The Commission has proposed that Member States add a REPowerEU chapter to their recovery plans to enable them to better target the pandemic recovery funds to the objective of lifting the EU's dependence on Russian fossil fuels. State aid rules fully apply to the reforms and investments included in such REPowerEU chapters. The Commission anticipates that stimulus from NextGenerationEU investment could boost the EU's economic growth by 1.5 % by 2027 and support the creation of 2 million new jobs.
European Commission endorses final Member State recovery and resilience plan (see here)	On 8 September 2022, the Commission endorsed the Netherlands' €4.7 billion recovery plan, submitted on 8 July 2022. This was the final Member State recovery plan to be submitted, as earlier indicated in the Commission's first Report on implementation of Recovery and Resilience Facility (RRF) in March 2022 (*see Jones Day COVID-19 Update No. 78 of 4 March 2022*). As above-mentioned, Member State recovery plans set out the reforms and public investment projects foreseen for implementation with the support of the RRF, the key component of NextGenerationEU, the EU's historic recovery fund. In evaluating Member State plans under the RRF Regulation, notably, the RRF guidelines make clear that the investment projects included in Member State recovery plans must comply with State aid rules (*Jones Day Commentary, "EU Member State COVID-19 Recovery Plans Must Comply with State Aid Rules," March 2021, see here*). The Commission's appraisal of Member State plans will also, in particular, determine whether the plans dedicate at least 37% of expenditure to investments and reforms that pursue climate objectives and 20% to the digital transition. The Commission's approval remains pending for 1 Member State plan (Hungary (€7.2 billion) (see here). With respect to the Netherlands, the Council will have four weeks to adopt the Commission proposal for a Council Implementing Decisions for approval of the its recovery plan. Following the Council's approval, the Commission will authorize disbursements to the Netherlands based on the satisfactory fulfilment of the milestones and targets outlined in its recovery plan, reflecting progress on the implementation of the investments and reforms. With respect to Hungary, the Commission launched a "conditionality mechanism of the rule of law procedure" against Hungary in April 2022. On 18 September 2022 (see here), it proposed budget protection measures to the Council under the EU's conditionality regulation. The Commission has proposed: (i) a suspension of 65% of the commitments for three operational programs under cohesion policy, and (ii) a prohibition to enter into legal commitments with the public interest trusts for programs implemented in

	direct and indirect management. Additional risks for the Hungarian economy would be the result of a failure to approve Hungary's national recovery plan for the disbursement of approx. EUR 7 billion in NextGenerationEU grants. The Recovery and Resilience Scoreboard provides an overview of how implementation of the RRF and national plans is progressing (see here).
Commission approves up to €5.2 billion of public support for second IPCEI in hydrogen value chain (see here)	On 21 September 2022, the Commission approved up to €5.2 billion of public support by 13 Member States for "Hy2Use", the second IPCEI (Important Project of Common European Interest) in the hydrogen value chain. To recall, hydrogen was identified by the EU as an area for coordinated investment by Member States and industry in the form of new IPCEIs (in addition to sectors such as next-generation Cloud and Edge Infrastructure and Services, health, and microelectronics). Such IPCEI initiatives are a component of the green and digital transition and respond to the ambitions of the Updated Industrial Strategy of May 2021 to ensure that Europe's industrial goals take full account of the new circumstances following the COVID-19 crisis, as noted in the Commission's Annual Single Market Report 2022 (*see Jones Day COVID-19 Update No. 77 of 23 February 2022*). The IPCEI Hy2Use project involves 29 companies and 35 projects from 13 Member States. The project seeks to boost the supply of renewable and low-carbon hydrogen and to enable the development and first industrial deployment of clean and innovative hydrogen technologies in industrial sectors (e.g., cement, steel and glass) not covered by the first hydrogen IPCEI, the €5.4 billion "Hy2Tech" project, which focuses on end-users in the mobility sector (approved on 15 July 2022 (see here)). As stated by Executive Vice-President and Commissioner for Competition Margrethe Vestager: "*Developing technologies for low carbon and, in particular, green hydrogen, and building the necessary infrastructure for its deployment … will also take us one step closer to a diversified combination of energy sources in Europe, and hopefully many steps away from dependence to Russian fossil fuels, in line with the REPowerEU Plan.*" Member States are currently in the process of designing other IPCEIs relating to the hydrogen value chain and other key technologies. In this respect, Commissioner Vestager also emphasized that "*IPCEI rules are not the only relevant ones to contribute to achievement of our environmental and energy objectives. Actually, the main applicable rules are those of the Climate, Environmental protection and Energy Aid Guidelines (CEEAG), which were updated at the beginning of the year.*" (*see Jones Day publications: New Guidelines on State Aid for Climate, Environmental Protection, and Energy in the European Union*, February 2022; *and EU Revises State Aid Rules for Important Projects of Common European Interest*, February 2022).
European Commission approves further schemes under Ukraine	The Commission continues to approve additional measures under the State aid Temporary Crisis Framework for State Aid measures in the context of Russia's invasion of Ukraine. The Crisis Framework, adopted by the Commission on 23 March 2022, sets

Temporary Crisis Framework (see here)	out the criteria for Member States to support businesses in the context of Russia's invasion of Ukraine and its serious disruption to the EU economy (see *Jones Day COVID-19 Update No. 80 of 25 March 2022*). To recall, in adopting this Crisis Framework, the Commission noted that the conflict had significantly impacted the energy market, and steep rises in energy prices had affected various economic sectors, including some of those particularly affected by the COVID-19 pandemic, such as transport and tourism. The conflict also disrupted supply chains for both EU imports from Ukraine (in particular, cereals and vegetable oils) and EU exports to Ukraine. Among the latest schemes under the Crisis Framework (until 23 Sept 2022): – €20 million Greek scheme to support newspaper publishers in context of Russia's invasion of Ukraine – €96 million Italian scheme to support companies in Lombardy in the context of Russia's invasion of Ukraine – €50 million Lithuanian scheme to support companies in the context of Russia's invasion of Ukraine – €14 million Estonian scheme to support companies active in the food and beverages production sectors in in the context of Russia's invasion of Ukraine – €4 billion Romanian scheme to support companies in the context of Russia's invasion of Ukraine Notably, the Crisis Framework complements the various possibilities for Member States to design measures in line with existing EU State aid rules. For instance, State aid measures under the Crisis Framework may be cumulated with aid granted under the COVID-19 Temporary Framework, provided that their respective cumulation rules are respected. The Crisis Framework, applicable since 1 February 2022, will be in place until 31 December 2022. During its period of application, the Commission will keep the Framework under review in light of developments regarding the energy markets, other input markets, and the general economic situation. Prior to the Crisis Framework's end date, and in view of maintaining legal certainty, the Commission will assess whether it should be prolonged.
European Commission approves further schemes under COVID Temporary Crisis Framework (see here and here)	The Commission has adopted a significant number of State aid measures under Article 107(2)b, Article 107(3)b and under the State aid COVID Temporary Crisis Framework adopted in March 2020. With certain exceptions, the Temporary Framework applied until 30 June 2022.* Among the latest schemes (until 23 September 2022): • €380 million Italian investment support scheme towards a sustainable recovery in the context of the coronavirus pandemic. ** Exceptions notably include the possibility for Member States to (i) create direct incentives for private investments (until 31 December 2022) and (ii) provide solvency support measures (until 31 December 2023) aimed at easing access to equity finance for smaller companies*

TRADE / EXPORT CONTROLS

European Commission publishes 40th Annual Report on EU's Anti-Dumping, Anti-Subsidy and Safeguard activities in 2021 (see here)	On 19 September 2022, the European Commission published the 40th Annual Report on the EU's Anti-Dumping, Anti-Subsidy and Safeguard activities and the Use of Trade Defence Instruments by Third Countries targeting the EU in 2021. The Report indicates that despite ongoing COVID-19 related difficulties in 2021, the Commission maintained the vigorous application of EU trade defence instruments (TDI). According to the Report, the Commission's well-tested working methods, developed early in the pandemic, enabled it to conduct all investigations to the highest standards and to safeguard EU producers against injurious unfairly traded imports. Notably: – As of end-2021, the EU had 163 definitive trade defence measures in force (an increase of 13 measures over 2020): 109 definitive anti-dumping measures (extended in 31 cases), 19 anti-subsidy measures (extended in 1 case), and 3 safeguard measures. These measures, according to the Report, protected over 462,000 direct jobs. – The Report further notes that in 2021, the Commission put in place improved monitoring practices, given the primary concern that the enforcement and effectiveness of trade defence measures continue to strengthen their key role in building more resilient European businesses. The Commission's greater scrutiny, in particular, anticipated the risk of increased avoidance of paying duties in the post-pandemic recovery period. – A total of 54 products under trade defence measures, for example, were subject to special monitoring as of end-2021. In this respect, the Commission, e.g., alerted national customs authorities to pay particular attention to imports of products subject to TDI measures where concerns had arisen, and provided OLAF (European Anti-Fraud Office) with information signifying fraudulent activity on imports. A Commission Staff Working Document (SWD) accompanies the Report and provides further information and statistics (see here).
European Commission publishes proposed Regulation establishing a Single Market Emergency Instrument (see here)	On 19 September 2022, the European Commission released its proposed Regulation for a Single Market Emergency Instrument (SMEI), which seeks to establish a crisis governance framework. The proposed SMEI presents a toolbox aimed at addressing the EU's structural shortcomings revealed by the COVID-19 pandemic, which impeded the ability to provide an effective and coordinated response to the crisis. As stated by Executive Vice-President and Commissioner for Competition Margrethe Vestager, "*the Covid 19 crisis showed us our Single Market isn't perfect. It is strong, but not unbreakable*." For example, unilateral measures by Member States, including intra-EU export and travel restrictions, caused fragmentation and aggravated the crisis. The SMEI, which complements other EU legislative measures for crisis management, sets out a crisis management framework to identify threats to the Single Market and to preserve its smooth functioning by:

	• Establishing a new crisis governance mechanism to monitor the Single Market, identify different levels of risk, and coordinate an appropriate response, comprised of the following stages: – Contingency mode enables the Commission to undertake measures at all times to prepare for possible crises (e.g., preparing crisis protocols, training and simulations for Member States; the establishment of an early warning systems); – Vigilance mode can be activated in case of a threat of significant disruption in the supply of goods or services of strategic importance with the potential to escalate into a Single Market emergency. Vigilance mode measures include, for example, Member State monitoring of supply chains of strategically important goods and services and building up strategic reserves in these areas; and – Emergency mode is to be activated in the event of a crisis of wide-ranging impact on the Single Market that severely disrupts free movement or the functioning of critical supply chains. Emergency mode aims at safeguarding, for example, free movement in the Single Market through a blacklist of prohibited restrictions and, more generally, through reinforced and rapid scrutiny of unilateral restrictions. Additionally, and only when the emergency mode has already been activated, the Commission may also make use of last-resort measures under extraordinary circumstances, which require a separate activation step. In this case, for instance, the Commission may issue targeted (including binding) information requests to economic operators and request them to accept priority-rated orders for crisis-relevant products, which firms must either comply with or provide serious reasons justifying refusal. An advisory group, chaired by the Commission and composed of one representative from each Member State, would advise the Commission on appropriate measures for preventing or addressing the impact of a threat of disruption or a crisis on the Single Market, while ensuring adequate coordination. Representatives of other crisis-relevant actors (e.g. European Parliament, EEA states, or economic operators and stakeholder organizations) could be invited to participate as observers. The European Parliament and Council of the EU will now discuss the proposed Regulation.
G7 Trade Ministers Meeting (see here)	On 14-15 September 2022, the G7 Trade Ministers met in Neuhardenberg, Germany, including the participation of Executive Vice-President and European Commissioner for Trade, Valdis Dombrovskis. The G7 Trade Ministers' work process is led by Germany's Federal Minister for Economic Affairs and Climate Protection, Robert Habeck, until 31 December 2022. Germany is pursuing the following work priorities under the so-called "G7 Trade Track": – Creating open, fair, resilient and sustainable supply chains; – Contribution of trade to the fight against the coronavirus pandemic;

– Digital and sustainable transformation of the global trading system;
– Strengthening multilateralism through global trade policy; and
– Ensuring rules-based free trade that takes into account fair social, environmental and human rights standards.

At this latest G7 Trade Ministers meeting, discussions focused on the impact of Russia's war of aggression, improving the stability of supply chains, reforming global trade regulations, and tackling unfair competition.

On ensuring a stable and sustainable supply of goods, the G7 Trade Ministers emphasized that countries must put their trade relationships on a broad basis to safeguard the robustness of economies if supplies from one trade partner are disrupted. In this respect, Federal Minister Habeck stated: "*Diversifying our trade relationships is a core task, as the coronavirus pandemic, the impact of climate change and geo-economic tensions have shown the importance of diversification. For this we need courage and determination to bring about a strategic realignment in trade policy*."

With respect to critical raw materials, for example, the G7 will further intensify work towards building responsible, sustainable, and transparent critical minerals supply chains by establishing a strategy based on international cooperation, policy, and financial tools. This includes addressing export restrictions and trade barriers at the international level.

On reforming the WTO and its rules, the G7 Trade Ministers re-affirmed the commitment to strengthening transparency, fair competition, and the rule of law, particularly in light of global crises and protectionist trade policy. Such reforms would include, for instance, creating a well-functioning dispute settlement system accessible to all WTO Members by 2024.

MEDICINES AND MEDICAL DEVICES

European Commission proposes Council Recommendation for a new approach on cancer screening (see here)	On 20 September 2022, the Commission published a proposal for a Council Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening. The Proposal seeks to introduce new best practices to improve cancer screening, in view of replacing the current 20-year old recommendations, which are urgently in need of updating. Furthermore, the Proposal seeks to *"fill the gap created by the impact of COVID-19 on cancer diagnosis and care…. [D]uring the pandemic, in most of the EU, cancer screening programmes largely stopped or slowed down. An estimated 100 million cancer screening tests were not performed in Europe during the pandemic"*, as stated by European Commissioner for Health and Food Safety, Stella Kyriakides,(see here). The Proposal's stated objectives include, in particular: – Supporting the development of the EU-supported Cancer Screening Scheme (announced in the 2021 Europe's Beating Cancer Plan, see here) to ensure that 90% of the EU population who qualify for breast, cervical and colorectal cancer screenings are offered screening by 2025;

- Sharing data on cancer screening, including through the planned European Health Data Space (*Jones Day COVID-19 Update No. 84 of 17 May 2022*) ;
- Extending breast cancer screening to women between 45 and 74 years of age;
- Prioritizing cervical cancer screening by testing for human papilloma virus (HPV) for women aged 30 to 65 and supporting its eradication through the uptake of vaccination below 15 years of age;
- Extending cancer screening programs to lung and prostate cancer as well as to gastric cancer in countries or regions with the highest gastric cancer incidence and death rates; and
- Taking into account the latest scientific knowledge and innovative technologies, and considering the introduction of novel cancer screening programmes based on minimally invasive methods.

To achieve those objectives, the Proposal recommends Member State actions, such as:

- Implementing accessible cancer screening programs that are in accordance with European guidelines with quality assurance, as well as with data protection legislation;
- Registering and managing screening data (i.e. data of all screening tests, assessments, final diagnoses and research) by making available centralized data systems that are compliant with data protection legislation;
- Monitoring the process and outcome of organized cancer screening and quickly reporting the results: Data and information should be appropriately registered, collected, stored and managed using the European cancer information system to allow the monitoring.
- Introducing promising novel screening tests: This should only be considered following their proven effectiveness, taking into account international research results.

The Proposal will now be discussed by Member States before its adoption by the Council of the EU.

The Commission's Q&A provides further information on the Proposal (see here).

HaDEA issues call for proposals for €5 million project to support dialogue on public procurement in health sector and crises preparedness (see here)

On 15 September 2022, the Commission's European Health and Digital Executive Agency (HaDEA) called for proposals to support a dialogue on public procurement in the health sector and crises preparedness.

In presenting the call for proposals, the Commission indicates that the COVID-19 pandemic highlighted the need for coordination and cooperation at EU and Member State level in the health sector, and exacerbated the existing weaknesses in the supply chain, including in the public procurement at Member State level.

The proposed project, with an announced €5 million budget, intends to

	support Member States in organizing a thorough assessment of public procurement in the health sector involving Member State bodies at national, regional and local level, as well as relevant stakeholders. The proposed project seeks a high coverage of Member States, and ideally around 12 Member-States. Project deliverables include, e.g.: – Mapping of the public procurement environment in the health sector in the Member States covered; – New strategies for public procurement in health sector tailored to the needs of the Member State or region concerned as well as an implementation plan based notably on: Discussion of all recommendations in order to develop a first draft national/regional strateg(y)ies with the involvement of all stakeholders and decision makers; and – Dissemination of the project's results in a final conference with a European dimension. The expected results of the proposed project include, in particular: – developing and improving national and regional strategies on public procurement increasing the resiliency and efficiency throughout the Union; – increasing future coordination and cooperation of the bodies involved; – strengthening preparedness for future health crises. The call for proposals is open until 23 February 2023.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission proposes European Media Freedom Act (see here)	On 16 September 2022, the Commission presented a proposal for a Regulation establishing a common framework for media services in the internal market (European Media Freedom Act). The Proposal arises from the EU's efforts to support media freedom and pluralism, address disinformation, and promote democratic participation, as set out under the European Democracy Action Plan (see here). As noted in the Proposal, the COVID-19 pandemic exacerbated the economic fragility of the media sector. To address this issue, the Proposal aims at strengthening the financial stability and editorial independence of media service providers by focusing on four objectives: (i) Fostering cross-border activity and investment in media services by harmonizing certain elements of the diverging national media pluralism frameworks; (ii) Increasing regulatory cooperation and convergence through cross-border coordination tools and EU-level opinions and guidelines;

	(iii) Facilitating provision of quality media services by mitigating the risk of undue public and private interference in editorial freedom (e.g., seeking to ensure that journalists and editors can work without interference, including when protecting their communications and sources); and (iv) Ensuring transparent and fair allocation of economic resources in the internal media market by enhancing transparency and fairness in audience measurement and allocation of state advertising. In particular, towards reducing the risk of undue interference in editorial freedom, the Proposal provides that Member States, including their national regulatory authorities and bodies, shall not: • Deploy spyware* in any device or machine used by media service providers, their employees or family members, unless justified on grounds of national security. This provision builds on protections provided by the ePrivacy Directive, the Law Enforcement Directive, and the Directive on attacks against information systems; • Interfere in or try to influence in any way, directly or indirectly, editorial policies and decisions by media service providers; • Detain, sanction, intercept, subject to surveillance or inspect media service providers or their family members on the ground that they refuse to disclose information on their sources, unless justified by an overriding requirement in the public interest. The Proposal will now undergo discussion by the European Parliament and the Council of the European Union. Once adopted, the European Media Freedom Act will be directly applicable across the EU. Accompanying the Proposal, the Commission also adopted a Recommendation (see here) to encourage internal safeguards for editorial independence. * The Proposal defines "spyware" as follows: *"any product with digital elements specially designed to exploit vulnerabilities in other products with digital elements that enables the covert surveillance of natural or legal persons by monitoring, extracting, collecting or analysing data from such products or from the natural or legal persons using such products, in particular by secretly recording calls or otherwise using the microphone of an end-user device, filming natural persons, machines or their surroundings, copying messages, photographing, tracking browsing activity, tracking geolocation, collecting other sensor data or tracking activities across multiple end-user devices, without the natural or legal person concerned being made aware in a specific manner and having given their express specific consent in that regard."*
European Commission proposes Cyber Resilience Act (see here)	On 15 September 2022, the Commission adopted a proposal for a Regulation on cybersecurity requirements for products with digital elements (Cyber Resilience Act). The Proposal seeks to reinforce cybersecurity rules to ensure more secure hardware and software products (*see Jones Day Alert, European Commission Proposes Legislation Imposing New Cybersecurity Requirements on Digital Products, September 2022*). The Proposal is part of the EU Cybersecurity Strategy (see here) and will

complement the existing European cybersecurity framework, i.e., the NIS 1 Directive, soon to be replaced by the NIS 2 Directive (*see also* Jones Day COVID-19 Update No. 84 of 17 May 2022) and the Cybersecurity Act (*see also Jones Day Commentary, The EU Cybersecurity Act is Now Applicable, June 2019.*)

As explained in the Commission's Impact Assessment Report on the Proposal (see here), both companies and consumers are increasingly dependent on products with digital elements, particularly since the COVID-19 pandemic, which accelerated the digitization of society and the spread of telework. The importance and impact of cyberattacks are also significantly increasing and are being used as an economic and geopolitical weapon.

To address such challenges, the Proposal aims to safeguard EU businesses and consumers buying or using digital products against the risks of inadequate cybersecurity features by laying down certain rules, such as:

- Essential requirements for the design, development, production, delivery, and maintenance of products with digital elements to protect against cyber threats.

- Obligations for manufacturers, such that, e.g., before placing a digital product on the market, manufacturers must document all related cybersecurity risks; report vulnerabilities and incidents; provide for effective vulnerability handling processes for the expected product life cycle or for a period of five years.

- Obligations for importers and distributors concerning cybersecurity with respect to products entering the market.

- Conformity assessment process designed to demonstrate compliance with cybersecurity requirements.

- Surveillance and enforcement, such that each Member State must appoint a market surveillance authority responsible for the enforcement of the regulation, including the ability to impose fines (up to €15 million or up to 2.5% of an undertaking's total global turnover)..

The Proposal will now undergo discussion by the European Parliament and the Council of the European Union. If adopted, upon entry into force, manufacturers, notified entities, and Member States will have two years to adapt to the new requirements (except for the obligation to report vulnerabilities and incidents, which will only apply after one year).

Further information on the Proposal is also provided in the Commission's accompanying Q&A (see here).

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