



COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 99 | 17 March 2023

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.

*This COVID-19 Update will soon be transitioning to the **new EU Emergency Response Update – Key Policy & Regulatory Developments**, which will continue to cover key regulatory developments related to EU emergency responses, including in particular, to the COVID-19 and Ukraine-Russia situations.*

LATEST KEY DEVELOPMENTS

Competition & State Aid

- European Commission conducts public consultation on mid-term evaluation of Recovery and Resilience Facility
- European Commission amends General Block Exemption rules to further promote green and digital transition
- European Commission adopts new Temporary Crisis and Transition Framework for State aid to support economy in context of Russia's invasion of Ukraine
- European Commission approves further schemes under Temporary Crisis and Transition Framework for State aid to support economy in context of Russia's invasion of Ukraine

Trade / Export Controls

- European Commission publishes Communication and proposed Critical Raw Materials Act
- European Commission publishes 2022 General Report on Activities of the European Union
- Council of the European Union prolongs individual sanctions over Russia's military aggression against Ukraine

Medicines and Medical Devices

- Council of the European Union adopts Regulation extending the deadline for the certification of medical devices
- European Commission publishes 2022 General Report on Activities of the European Union

Cybersecurity, Privacy & Data Protection

- Joint EMA/HMA Big Data Steering Group publishes Clusters of Excellence Discussion Paper

COMPETITION & STATE AID

State Aid

European Commission conducts public consultation on mid-term evaluation of Recovery and Resilience Facility (see [here](#))

On 16 March 2023, the Commission launched a public consultation in view of preparing the mid-term evaluation of the Recovery and Resilience Facility (RRF), established in February 2021 by [RRF Regulation \(EU\) 2021/241](#) (running until end-2026) in response to the COVID-19 pandemic to support faster and more resilient Member State recovery.

The RRF is the core instrument of the €800 billion NextGenerationEU recovery plan for Europe's green and digital transformation. To date, the Commission has disbursed a total of over €144 billion under the RRF, in both grants (€97 billion) and loans (€47 billion). The Commission indicates that many more disbursements are expected as the second half of the RRF's lifetime approaches.

Member State recovery plans set out the reforms and public investment projects foreseen for implementation with the RRF's support. 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 public consultation seeks to assess the effectiveness and relevance of the RRF's implementation in responding to the RRF Regulation's objectives and bringing benefits to the EU. The consultation includes questions such as:

- *“In your view, how important has the Recovery and Resilience Facility been for the recovery of the EU economy from the COVID-19 crisis”?*
- *“In your view, to what extent has the Recovery and Resilience Facility created unnecessary administrative burden and complexity for Member States' administrations”?*

Next steps. The Commission will take into account input received (to be summarized in a synopsis report) in preparing its mid-term evaluation report, anticipated in Q1 2024. Where appropriate, the evaluation shall be accompanied by a proposal for amendments to the RRF Regulation.

The Commission further indicates that a series of targeted consultations aimed at specific categories of stakeholders throughout the year will complement the present consultation, which runs until 8 June 2023.

European Commission amends General Block Exemption rules to further promote green and

On 9 March 2023, the Commission endorsed a targeted amendment of the General Block Exemption Regulation (GBER) in view of further facilitating, simplifying and accelerating support for the EU's green and digital transitions.

Together with the new Temporary Crisis and Transition Framework for State aid, (see *below item*), this amended GBER, in particular, is intended to better

digital transition
(see [here](#))

enable Member States to grant necessary support for key sectors in line with the Green Deal Industrial Plan (see also [Jones Day COVID-19 Update No. 97 of 14 February 2023](#)).

To recall, the GBER declares specific categories of State aid, where fulfilling certain conditions, as compatible with EU law. The GBER exempts such categories from prior notification to and approval by the Commission. This enables Member States to directly grant aid and to inform the Commission on an *ex-post* basis.

In addition to affording Member States greater flexibility to design and implement support measures in sectors viewed as key to reaching climate neutrality and a net-zero industry, the amended GBER will also contribute to tackling economic consequences of Russia's war against Ukraine and the COVID-19 pandemic (e.g., high energy prices). In particular, the amended rules:

- Expand and streamline the possibilities for aid in areas such as environmental protection and energy (e.g., supporting the rollout of renewable energy, green mobility and investments to increase energy efficiency);
- Bolster the implementation of certain projects involving beneficiaries across several Member States, such as Important Projects of Common European Interest ("IPCEI") in the research and development field, by raising aid levels and notification thresholds;
- Block exempts aid measures established by Member States to regulate prices for energy such as electricity, gas and heat produced from natural gas or electricity;
- Significantly increase notification thresholds for environmental aid and Research, Development and Innovation ("RDI") aid; and
- Extend the GBER until end-2026 for legal certainty and regulatory stability.

Next steps: Now that the Commission's has endorsed the English text of the amended GBER, it will be formally adopted following the translation of the text in all official languages of the EU. It will enter into force on the day following its publication in the Official Journal of the European Union.

European Commission adopts new Temporary Crisis and Transition Framework for State aid to support economy in context of Russia's invasion of Ukraine (see [here](#))

On 9 March 2023, the Commission adopted a Communication on a Temporary Crisis and Transition Framework for State Aid measures to support the economy following the aggression against Ukraine by Russia ("new TCTF").

The new TCTF replaces the previous [Temporary Crisis and Transition Framework](#) ("previous TCTF", adopted on 28 October 2022 and which already replaced the TCTF adopted on 23 March 2022 and amended on 20 July 2022) to enable Member States to support the economy in the context of Russia's war against Ukraine.

The new TCTF continues to enable Member States to cushion the economic impact of Russia's aggression of Ukraine, while also closely focusing on enhancing support measures in sectors viewed as key to transitioning to a net-zero economy in line with the Green Deal Industrial Plan (see also [Jones](#)

[Day COVID-19 Update No. 97 of 14 February 2023](#)).

The new TCTF amends and prolongs measures from the previous TCTF, such as by:

- Extending and amending measures for transitioning to a net-zero industry, e.g., schemes for accelerating the rollout of renewable energy and energy storage, and schemes for the decarbonization of industrial production processes:
 - Member States may now support such schemes for an extended period (until 31 December 2025);
 - Such schemes are amended in scope to further facilitate their design and effectiveness by, e.g.:
 - (i) Expanding the possibilities to support the deployment of all types of renewable energy sources;
 - (ii) Granting aid for less mature technologies (e.g., renewable hydrogen), without competitive bidding, but subject to certain safeguards;
 - (iii) Raising aid ceilings and simplifying aid calculations.
- Introducing new measures (applicable until 31 December 2025) to further accelerate investments in sectors identified as key to transitioning to a net-zero economy by enabling investment support for the manufacturing of strategic equipment (e.g., batteries, solar panels, wind turbines, heat-pumps, electrolysers and carbon capture usage/storage) and for production of key components and for production and recycling of related critical raw materials.

Member States may undertake measures, such as:

- Designing schemes aimed at simplicity/effectiveness and providing support capped at a certain percentage of investment costs and nominal amounts, depending on the investment's location and beneficiary's size. Additional provisions include, for instance, allowing for higher support for small and medium-sized enterprises and companies located in disadvantaged regions.
- In exceptional cases, providing higher support to individual companies, where there is a real risk of the diversion of investments away from Europe, subject to various safeguards (e.g., using such option only for (i) investments occurring in assisted areas, as defined in the applicable regional aid map; or (ii) cross-border investments involving projects located in at least three Member States, with a significant part of the overall investment taking place in at least two assisted areas).

Other provisions from the previous TCTF (remaining applicable until 31 December 2023) are more centered on easing the impact of the immediate Ukraine crisis situation. These concern limited amounts of aid; liquidity support in form of State guarantees and subsidized loans; aid to compensate for high energy prices; and measures aimed at supporting electricity demand reduction.

The Commission applied the new TCTF as from 9 March 2023 to all measures notified as of 9 March 2023, as well as to measures notified prior to that date.

Next steps. The Commission will review all sections under the TCTF before 31 December 2023 on the basis of important competition and economic considerations and international developments.

European Commission approves further schemes under Temporary Crisis and Transition Framework for State aid to support economy in context of Russia's invasion of Ukraine (see [here](#))

The Commission approved additional measures under the State aid Temporary Crisis and Transition Framework (TCTF) to support the economy in the context of Russia's invasion of Ukraine and in sectors key to accelerating the green transition and reducing fuel dependencies under the (i) new TCTF (applied as from 9 March 2023); and (ii) previous TCTF (replaced by new TCTF on 9 March 2023) (*see also above item on new TCTF*).

Among the most recently approved State aid schemes:

(i) under the new TCTF (as from 9 March 2023)

- €650 million Slovenian scheme to support companies facing increased energy costs in the context of Russia's war against Ukraine.
- €1.75 million Slovenian scheme to support the apple and pear production sector in the context of Russia's war against Ukraine.
- Amendments to two existing Hungarian schemes, including an overall €6.18 billion budget increase, to support companies in the context of Russia's war against Ukraine. The amendments were approved under the previous TCTF and further amended and in part prolonged on 9 March 2023 with the adoption of the new TCTF.
- €100 million Irish scheme to support the microelectronics-manufacturing sector in the context of Russia's war against Ukraine.

(ii) under the previous TCTF (up to 8 March 2023)

- €18 million Irish scheme to support road haulage operators in the context of Russia's war against Ukraine.
- Amendment to an existing Italian guarantee scheme, including up to a €3 billion budget increase, for the reinsurance of natural gas and electricity trade credit risk in the context of Russia's war against Ukraine.
- €95 million Finnish scheme to support the primary agricultural and aquaculture production sector in the context of Russia's war against Ukraine.
- €12 million Belgian scheme to support companies (open to companies of all sizes active in those sectors most affected by the rise of energy prices, such as accommodation and manufacturing of food products, established in the Brussels-Capital region) in the context of Russia's war against Ukraine.
- €1.5 million Slovenian scheme to support small and medium-sized enterprises in the context of Russia's war against Ukraine.

TRADE / EXPORT CONTROLS

European Commission publishes proposed Critical Raw Materials Act and related Communication (see [here](#) and [here](#))

On 16 March 2023, the European Commission published a set of measures aimed at building on the strengths of the EU's Single Market and external partnerships to diversify and reinforce the resilience of EU supply chains for critical raw materials (CRM) that are essential to many strategic sectors, including the net zero industry, digital, aerospace, and defence sectors.

The Commission notes that these measures build on, in particular, actions initiated under the Commission's 2020 Action Plan on critical raw materials (see also [Jones Day COVID-19 Update No. 21 of 8 September 2020](#)). The Commission also further emphasized the EU's need to mitigate supply chain risks related to strategic dependencies, as highlighted by shortages triggered by the COVID-19 pandemic (e.g. for semiconductor chips) and the energy crisis following Russia's invasion of Ukraine.

The Commission's measures comprise the following:

(i) The **Communication on a secure and sustainable supply of critical raw materials in support of the twin transition** outlines steps for scaling up and accelerating the EU's primary and secondary raw materials supplies, based on three pillars:

- Developing the EU's CRM value chain (e.g., through the below-discussed proposed draft Critical Raw Materials Act);
- Boosting supply diversification and partnering in a mutually beneficial manner in support of global production (e.g. establishing a "Critical Raw Materials Club" for all like-minded countries seeking to reinforce global supply chains); and
- Fostering sustainable sourcing and promoting circularity (e.g., proactively using EU trade agreements to support sustainable development, as reflected in the [Commission Communication](#) (22 June 2022) setting out how to further enhance the contribution of trade agreements to sustainable development).

(ii) The **proposed Critical Raw Materials Act***, as referred to in the above-mentioned Communication, aims at providing a regulatory framework to support the development of domestic capacities and strengthen sustainability of the EU's CRM supply chains, notably by:

- Providing an updated list of CRMs, in addition to identifying a list of "strategic raw materials" deemed as crucial to green and digital technologies and for defence and space applications, but which face potential supply risks in the future. This strategic raw material list will be reviewed at least every 4 years.
- Setting clear benchmarks for domestic capacities along the strategic raw material supply chain by 2030, including:
 - By 2030, significantly increasing EU capacities for each strategic raw material so that, overall, EU capacity approaches or reaches the following benchmark capabilities:
 - (i) EU extraction capacity to extract the ores, minerals or concentrates needed to produce at least 10% of the EU's annual

consumption of strategic raw materials, to the extent that the EU's reserves allow for this;

(ii) EU processing capacity to produce at least 40% of the EU's annual consumption of strategic raw materials; and

(iii) EU recycling capacity to produce at least 15% of the EU's annual consumption of strategic raw materials.

- Setting clear benchmarks for diversifying EU supply by 2030, such that by 2030, the EU's annual consumption of each strategic raw material at any relevant stage of processing can rely on imports from several third countries, none of which provides over 65% of the EU's annual consumption.
- Easing administrative burdens and simplifying permitting procedures for CRM projects in the EU. Selected strategic projects would also benefit from support for access to finance and shorter permitting timeframes.
- Seeking mutually beneficial partnerships with emerging markets and developing economies towards diversifying investment and promoting stability in international trade.

Next steps: The proposed Critical Raw Materials Act will undergo discussion and agreement by the European Parliament and the Council of the European Union in view of its adoption and entry into force.

** Proposal for a Regulation of the European Parliament and of the Council establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) 168/2013, (EU) 2018/858, 2018/1724 and (EU) 2019/1020.*

European Commission publishes 2022 General Report on Activities of the European Union (see [here](#))

On 15 March 2023, the European Commission released "The EU in 2022 – General Report on the Activities of the European Union."

The Report presents the EU's key activities of the EU in 2022, highlighting in particular the EU's response to Russia's war of aggression against Ukraine, such as the following:

- Ukrainian and European companies are supported through the [Supply Chain Resilience platform](#) addressing disruptions in international supply chains and [EU-Ukraine Solidarity Lanes Business Matchmaking platform](#) to find solutions to export agricultural products from Ukraine.
- A new [Regulation](#) has enabled all Ukrainian imports to enter the EU entirely duty and quota free, which the Commission recently [proposed](#) to extend by one year (currently set to expire in June 2023). Trade restrictions imposed on Ukraine before the war, such as anti-dumping and safeguard measures, were also suspended.
- The EU has been progressively imposing [sanctions against Russia](#) since March 2014, initially in response to the illegal annexation of Crimea and Sevastopol and the deliberate destabilization of Ukraine. The sanctions significantly expanded following Russia's military aggression against Ukraine, starting in February 2022, with a total of nine packages of restrictive measures adopted by end-2022.

The European Commission established the [Seize and Freeze Task Force](#) in March 2022 to ensure the efficient implementation of EU sanctions against listed Russian and Belarusian individuals and companies and to determine potential links between their assets and criminal activity. Working closely with international partners, including Ukrainian and U.S. authorities, the EU had frozen over €20 billion in Russian assets by end-2022.

The EU, its Member States and financial institutions together mobilized close to €50 billion in overall support for Ukraine by end-2022, including an unprecedented support package of up to €18 billion in the form of favorable loans, €19.7 billion in financial assistance, budget support and humanitarian assistance, and €3.1 billion in military assistance.

For further details on the 2022 General Report, see below section on Medicines and Medical Devices.

Council of the European Union prolongs individual sanctions over Russia's military aggression against Ukraine (see [here](#))

The EU relies on restrictive measures (sanctions) as one of its tools to advance its Common Foreign and Security Policy (CFSP) objectives, such as safeguarding EU's values, fundamental interests, and security; preserving peace; and supporting democracy and the rule of law.

Sanctions include measures such as travel bans (prohibition on entering or transiting through EU territories); asset freezes; prohibition on EU citizens and companies from making funds and economic resources available to the listed individuals and entities; ban on imports and exports (e.g., no exports to Iran of equipment that might be used for internal repression or for monitoring telecommunications), and sectoral restrictions.

Among the most recent developments to the EU sanctions regimes:

Russia: On 13 March 2023, the Council decided to extend restrictive measures by six months (until 15 September 2023) targeting those responsible for undermining or threatening the territorial integrity, sovereignty and independence of Ukraine. Such restrictions are subject to renewal every six months.

The sanctions apply to 1473 individuals and 205 entities (including the recent addition of 3 Russian banks, among which Alfa-Bank and Tinkoff Bank) to the list of those subject to a freezing of their assets, and EU citizens and companies are forbidden from making funds and economic resources available to them. Natural persons are additionally subject to a travel ban, which prevents them from entering or transiting through EU territories. The list of sanctioned persons and entities is subject to ongoing review and periodic renewals by the Council.

These sanctions, first introduced in 2014 in response to Russia's actions destabilizing the situation in Ukraine, have significantly expanded following Russia's military aggression against Ukraine, starting in February 2022 with the so-called first package of sanctions (see [here](#)) and now with the 10th package of sanctions (see [here](#)) adopted by the Council on 24 February 2023.* (see also [Jones Day COVID-19 Update No. 98 of 1 March 2023](#))

The EU restrictions also concern economic relations (e.g. certain import/export bans; certain bans on advisory/consultancy services) with the illegally annexed Crimea and the city of Sevastopol, the non-government

controlled areas of the Donetsk and Luhansk oblasts, as well as Zaporizhzhia and Kherson.

The European Commission's [Q&A](#) on the 10th package of sanctions provides further details (see [here](#)). The Q&A, in particular, specifies that none of the EU's sanctions adopted against Russia prevent the supply of agri-food, medical equipment or medicines for the general population in Russia. Also, no EU sanctions would prohibit third countries from purchasing Russian fertilizers.

A consolidated latest version of all Commission FAQs on implementation of sanctions adopted following Russia's military aggression against Ukraine is also available [here](#).

** An in-depth analysis of the 10th package of sanctions against Russia is available from the authors of the COVID-19 Update (see contact details below for Nadiya Nychay (Brussels) and Rick van 't Hullenaar (Amsterdam)).*

MEDICINES AND MEDICAL DEVICES

Council of the European Union adopts Regulation extending the deadline for the certification of medical devices (see [here](#))

On 7 March 2023, the Council adopted a Regulation extending the deadline for the certification of medical devices (*Regulation (EU) 2023/607 of 15 March 2023 amending Regulations (EU) 2017/745 (Medical Devices Regulation) and (EU) 2017/746 (In Vitro Medical Devices Regulation) on transitional provisions for certain medical devices and in vitro diagnostic medical devices*).

To recall, the Medical Devices Regulation ("MDR") and the In Vitro Medical Devices Regulation ("IVDR") introduced new and more robust conformity assessment rules for medical devices and additional requirements, such as on the designation and oversight of the so-called "Notified Bodies" (i.e., conformity assessment bodies). These rules gradually replace the old rules for medical devices (Directive 93/42/ECC); active implantable medical devices (Directive 90/385/ECC); and in vitro medical devices (Directive 98/79/EC).

The transition to compliance with the MDR and IVDR has been slower than anticipated by the Commission, which notes multiple reasons for delays:

- Few Notified Bodies are authorized to issue certifications of conformity under the new rules, and therefore have insufficient capacity to timely complete such certifications for all devices in need of certification (or re-certification). Many manufacturers, particularly those of small and medium size, are inadequately prepared to meet the stricter requirements under the new rules.
- The COVID pandemic and the war in Ukraine have further exacerbated the already strained European health system by impacting global supply chains, clinical investigations, and on-site audits. This threatens the continued adequate availability of medical devices in the EU.

In order to mitigate the risk of medical device shortages, the new Regulation extends the transition period for devices covered by a certificate or declaration of conformity issued under the old rules (so-called "legacy devices"). In particular, producers of medical devices will now have until 31 December 2027 for higher risk devices and until 31 December 2028 for medium and lower risk devices to meet the legal requirements. The granting

of extensions of the transition period depends on fulfilling certain conditions to ensure that only devices that are safe and for which manufacturers have already started the certification procedure will benefit from the additional time.

Furthermore, the new Regulation aims to reduce the risk of medical devices shortages by removing the rule on “sell-off” dates (i.e., the end date after which devices already on the market, but not yet with the final user, should be withdrawn). Only devices that comply with the previous EU law on medical devices will benefit from this rule, thereby allowing safe medical devices to remain longer on the market.

For further information, see also *Jones Day Commentary, “EU Commission Proposes Extended Deadlines to Comply with the Medical Device Regulation and In Vitro Diagnostic Regulation”, February 2023 ([here](#))*.

European Commission publishes 2022 General Report on Activities of the European Union (see [here](#))

On 15 March 2023, the European Commission released “The EU in 2022 – General Report on the Activities of the European Union.”

The Report presents the EU’s key activities of the EU in 2022, highlighting in particular the impact of the COVID-19 pandemic, such as:

- The digitalization of healthcare in the EU, as the development and adoption of digital health products and services accelerated with the COVID-19 pandemic, with telehealth becoming commonplace;
- The authorization of adapted vaccines to be used in a new booster program to prevent a rise in COVID-19 cases in light of evolving COVID-19 variants;
- The tackling of the long-term effects of COVID-19 infection, such as long COVID, including by funding research projects;
- The building of a strong European Health Union, which aims to better protect the health of EU citizens, prevent and prepare for future pandemics and improve Europe’s overall health system. To achieve this, the EU has, among other things:
 - adopted the Cross-Border Health Threats Regulation (*see also [Jones Day COVID-19 Update No. 90 of 28 October 2022](#)*);
 - established the Health Emergency Preparedness and Response Authority (HERA) (*see also [Jones Day COVID-19 Update No. 37 of 24 February 2021](#)*);
 - extended the EU Digital COVID Certificate (*see also [Jones Day COVID-19 Update No. 86 of 8 September 2022](#)*); and
 - increased the authority of the European Medicines Agency (EMA) to monitor the health sector and take actions to prevent medicine shortages and facilitate faster approvals of medicines to end a public health crisis;
- The close monitoring of the supply of important medicines and medical equipment by the EMA and Health Emergency Preparedness and Response Authority, as Russia’s war puts pressure on Member

States' health systems;

- The inclusion of the manufacturing of certain critical products, such as pharmaceuticals, medical devices and chemicals, in the expanded list of critical entities and sectors that need to take risk-management measures under the adopted NIS 2 Directive (Directive (EU) 2022/2555 on measures for a high common level of cybersecurity across the Union) (see also [Jones Day COVID-19 Update No. 93 of 1 December 2022](#)); and
- The proposal of the European Chip Act, which aims to build up the EU's semiconductor ecosystem. Chips and semiconductors are the building blocks of all electronic products, including medical devices. The global chips shortages has disrupted supply chains, causing product shortages including in medical devices.

For further details on the 2022 General Report, see above section on Trade / Export Controls.

CYBERSECURITY, PRIVACY & DATA PROTECTION

Joint EMA/HMA Big Data Steering Group publishes Clusters of Excellence Discussion Paper (see [here](#))

On 13 March 2023, the Joint Big Data Steering Group (BDSG) of the EMA (European Medicines Agency) and HMA (Heads of Medicines Agencies) released a Clusters of Excellence Discussion Paper aimed at embedding data analytics into the daily work of the EMRN (European Medicines Regulatory Network)*.

This Discussion Paper, which represents joint efforts of the EMRN agencies, addresses the following issues and related challenges facing these authorities:

- data access through varied sources and approaches;
- legal aspects of data access and use;
- capabilities in data management and analyses; infrastructure for coping with the ever-increasing amount of data;
- development of new methods to unlock the potential of the vast amounts of data that is being generated within the sphere of medicines and medical devices; and
- artificial intelligence (AI) in relation to the AI field's scope and complexity, and the use and trustworthiness of AI algorithms.

Concerning data access, in particular, the Discussion Paper emphasizes key challenges faced by the EMRN agencies (e.g., lack of a clear governance structure, lack of data standardization, and lack of knowledge about different national registries). To recall, various key challenges in data access remain unresolved (see [Jones Day COVID-19 Update No. 84 of 17 May 2022](#)).

Towards addressing these data access challenges, the Discussion Paper lists the following areas for collaboration between EMRN agencies:

- Foster data standards, including establishing common standards for

data linking; harmonizing core variables when developing data registries; exploring an engine for promoting common standards, i.e., Data Analysis and Real-World Interrogation Network (“DARWIN EU”), which provides real-time evidence on the use, safety and effectiveness of medicines for human use, including vaccines from databases across the EU (see [here](#)).

- Establish knowledge sharing forums, including enhancing structured dialogue and knowledge between different agencies working on the life cycle of medicines; sharing of metadata and sharing knowledge on ways of accessing data and how to resolve certain constraints.
- Allow access to data related to EMA procedures, for example, central data access structures should support use cases addressing research questions from EMRN agencies.

Next steps. The Discussion Paper’s observations and suggestions will contribute to the 2022 review of the BDSG work plan and review of the BDSG mandate (due in 2023). Existing bodies and initiatives will be leveraged, where feasible, to take forward the Discussion Paper’s key recommendations.

** The EMRN is a coordinated regulatory network of national competent authorities in the Member States of the European Economic Area working together with the European Medicines Agency and the European Commission.*

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