

EU EMERGENCY RESPONSE UPDATE

KEY POLICY & REGULATORY DEVELOPMENTS

No. 107 | 29 September 2023

This regular alert covers key regulatory developments related to EU emergency responses, including in particular, to COVID-19, Russia's war of aggression against Ukraine, and cyber threats. It does not purport to provide an exhaustive overview of developments.

This regular update expands from the previous COVID-19 Key EU Developments – Policy & Regulatory Updates (last issue [No. 99](#)).

LATEST KEY DEVELOPMENTS

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COMPETITION & STATE AID

State aid

European Chips Act enters into force (see [here](#))

On 21 September 2023, the European Chips Act entered into force (Regulation (EU) 2023/1781 of 13 September 2023 establishing a framework of measures for strengthening Europe's semiconductor ecosystem).

To recall, the Chips Act is part of the Commission's package of measures released in February 2022 (see [here](#)) aimed at ensuring the EU's security of supply and technological leadership in the field of semiconductors. (Micro-)chips or semiconductors are key building blocks for digital products, e.g., smartphones, computers, and medical equipment.

In announcing the Chips Act's entry into force, the Commission reminded, in particular, that the COVID-19 pandemic had exposed a weakness in the chips ecosystem within Europe and other regions worldwide, which have faced a chip shortage since 2020. According to the Commission, this has led to elevated prices, longer delivery times for vital medical equipment and consumer electronics, and an estimated 33% fall in car production in certain EU countries.

The Chips Act thereby seeks to increase the EU's resilience, safeguard supply, and reduce perceived external dependencies, based on three main pillars:

(i) The [Chips for Europe Initiative](#) aims at supporting large-scale technological capacity building. Notably, the [Chips Joint Undertaking](#) (Chips JU), a public-private partnership involving the EU, Member States and the private sector, will support activities such as establishing advanced pilot production lines to accelerate technology development. The Council's [Regulation on the Chips JU](#) of 25 July 2023 enables the Chips JU's establishment. The Regulation's entry into force, also on 21 September 2023, enables the start of implementing the Chips JU, the primary component of the Chips for Europe Initiative.

(ii) A [framework to ensure security of supply](#) seeks to spur public-private investments in manufacturing facilities for chipmakers and their suppliers. In particular, "first-of-a-kind" facilities, including those producing equipment used in semiconductor manufacturing, are expected to reinforce the EU's supply security.

State aid. In light of steep high barriers to entry and the capital intensity of the chips sector, the Commission notes that private investment in chips manufacturing facilities may likely require public support. In this respect, the Commission may consider approving State aid to such facilities under Article 107(3)(c) TFEU,* weighing relevant positive effects such as the following:

- The chips facility is "first-of-a-kind" in Europe (as defined in the Chips Act), such that an equivalent facility does not already exist in Europe;
- The public support covers a maximum of 100% of a proven funding gap, i.e., the minimum amount needed to ensure that such investments occur in Europe; and
- The chips facility would enhance [security of supply](#) for European businesses using chips in their products, e.g., where such facility

accepts to satisfy EU “priority-rated” orders (as provided in the Chips Act) such as orders from entities from critical sectors whose activities are disrupted or at risk of disruption due to chip shortages.

(iii) A monitoring and crisis response coordination mechanism will seek to anticipate supply shortages and provide responses in case of crisis. For example, early warning indicators in Member States will be used to trigger an EU-wide shortage alert. Such mechanism will allow the Commission to implement emergency measures such as prioritizing the supply of products particularly affected by a shortage, or carrying out common purchasing for Member States. These would be last-resort measures in the event of a crisis in the semiconductors sector.

The Chips for Europe Initiative is expected to mobilize €43 billion in public and private investments, including €6.2 billion of public funds (of which €3.3 billion from the EU budget), which comes in addition to €2.6 billion public funding already foreseen for semiconductor technologies. The objective is to double the EU's global market share in semiconductors from 10% to at least 20% by 2030.

Next steps. With the entry into force of the Chips Act, in particular, industry may apply to qualify their projects as “first-of-a-kind” facilities in order to benefit from various advantages (e.g., this status will be weighed as a positive element in the framework of State aid assessments and enable fast-tracking of permit granting procedures to facilitate the planning and establishment of such facilities).

The work of the newly established European Semiconductor Board has now also formally commenced. The Board is the advisory body serving as the primary coordination mechanism between the Commission (serving as Chair), Member States, and stakeholders for mapping/monitoring the EU's semiconductor value chain and preventing/responding to semiconductor crises with ad hoc emergency measures (e.g., information requests, priority-rated orders, and common purchasing).

** Article 107(3)(c) TFEU enables the Commission to approve State aid to facilitate the development of certain economic activities, if the positive effects of such State aid outweigh its potential negative impact on trade and competition.*

European Commission announces forum to improve selection and implementation of IPCEIs (see [here](#))

On 19 Sept 2023, the Commission announced its plans to launch the Joint European Forum for Important Projects of Common European Interest (IPCEIs).^{*} This Forum seeks to enhance the effectiveness of IPCEIs and to identify relevant strategic technologies for potential future IPCEIs.

To date, the Commission has approved up to €26.7 billion of State support for six IPCEIs in batteries, hydrogen and microelectronics ecosystems, involving 255 innovative projects from 21 Member States.^{**} This public support is anticipated to unlock a further €50 billion in private investments.

The Forum, gathering experts from the Commission, Member States, and stakeholders from industry, academia, etc., will notably focus on:

- Identifying and prioritizing strategic technologies for the EU economy as potential candidates for future IPCEIs;

- Providing a platform for Member States to share experiences and to develop best practices for the swift and well-founded selection, assessment and implementation of IPCEI projects; and
- Establishing standardized monitoring/evaluation procedures to assess the outcomes and possible shortcomings in the implementation phase of IPCEI projects.

Next steps. The Forum is anticipated to hold its first meeting in October 2023. The Commission's IPCEI website provides further information (see [here](#)), and a dedicated website for sharing the Forum's results is also foreseen.

** To recall, the EU's IPCEI rules seek to enable Member States and industry to jointly invest in ambitious pan-European projects in a transparent and inclusive manner, where the market alone appears unable to deliver and particularly where the risks are deemed as too large for a single Member State or company to assume. The Commission published a revised Communication on State aid rules for IPCEI on 25 November 2021 (see [Jones Day COVID-19 Update No. 69 of 29 November 2021](#)).*

*** The latest IPCEI was approved in June 2023 for up to €8.1 billion in Member State support for microelectronics and communication technologies (see [Jones Day EU Emergency Response Update No. 103 of 23 June 2023](#)).*

European Commission publishes Second Annual Report on implementation of Recovery and Resilience Facility (see [here](#))

On 19 September 2023, the Commission adopted its Second Annual Report on implementation of the Recovery and Resilience Facility (RRF), as required under the [RRF Regulation](#) (Regulation (EU) 2021/241 of 12 February 2021).*

To recall, the RRF is the key component of [NextGenerationEU](#), the EU's €806.9 billion plan for rebounding from the COVID-19 crisis. The RRF is also key to implementing [REPowerEU](#), launched in May 2022 in response to the energy market disruption caused by Russia's war against Ukraine. REPowerEU aims at enhancing the EU's strategic autonomy through diversified energy supplies, ceasing dependency on Russian fossil fuel, and accelerating the clean energy transition.

The RRF will provide up to €723 billion to finance reforms and investments (i.e., grants totaling €338 billion and €385 billion in loans). In particular, the RRF will support reforms and public investment projects foreseen for implementation under Member State recovery and resilience plans (see [Jones Day COVID-19 Update No. 64 of 18 October 2021](#)). Member States are also expected, in particular, to add a new REPowerEU chapter to complement their national recovery plans (see also [Jones Day COVID-19 Update No. 98 of 1 March 2023](#))

In evaluating the Member State plans, the RRF guidelines notably made clear that investment projects included in Member State recovery plans must comply with [State aid rules](#). The Commission published practical guidance for swift treatment of projects under State aid rules, as well as a number of sector-specific templates to help Member States design and prepare the State aid elements of their recovery plans (*Jones Day Commentary, "EU Member State COVID-19 Recovery Plans Must Comply with State Aid Rules," March 2021, see [here](#)*).

The Second Annual Report focuses on progress in areas such as:

- The RRF's ongoing implementation. All 27 Member State recovery plans were approved by December 2022. As of 1 September 2023, the Commission had received 31 payment requests from 19 Member States and disbursed a total amount of €153.4 billion.

The Council has also positively assessed four revised Member State recovery plans with REPowerEU chapters, and the Commission is assessing 16 revised plans.

The Report further notes that the Commission is assisting Member States with addressing the heightened challenges of implementing their national recovery plans in the midst of global instability, supply chain disruptions, the energy crisis, and inflation.

- Improved transparency of the RRF's implementation. Under amendments to the RRF Regulation, for instance, Member States must publish information on the 100 final recipients receiving the highest amounts of RRF funding on the [Recovery and Resilience Scoreboard](#), which provides an overview of progress on the RRF's implementation in the Member States and the EU as a whole.
- Safeguarding the EU's financial interests through strengthened control and audit efforts. Notably, in 2023, the Commission ramped up its control framework to further ensure the appropriate use of RRF funds. As of 1 September 2023, the Commission had carried out 14 risk-based ex-post audits on "milestones and targets" (conditional criteria for disbursing RRF payments to Member States), in view of seeking to verify the accuracy of Member State information on fulfilling such criteria (7 audits in each of 2022 and 2023).

In enhancing such safeguards, the Commission also took into consideration the recommendations of the European Parliament, Council, and European Court of Auditors, which had raised concerns over, for instance, the EU's limited options in verifying use of money from the RRF; and shortcomings in the Commission's assessment of national compliance with milestones and targets (see also [Jones Day EU Emergency Response Update No. 103 of 23 June 2023](#)).

Looking ahead. The RRF is entering the second half of its lifespan, with all payments of financial contributions to Member States to be made by 31 December 2026, with certain exceptions.

The Commission, working with the Member States and key partners, will maintain its focus on implementing the Member State recovery plans. The Commission aims at continuing to encourage and assist Member State efforts to optimize the RRF to expedite investments and reforms addressing key challenges, in view of ensuring a resilient recovery following the COVID-19 pandemic and in the context of a vastly changed economic and geopolitical context following Russia's war against Ukraine.

* For the first annual RRF implementation report, see [Jones Day COVID-19 EU Regulatory Update No. 78 of 4 March 2022](#)

TRADE / EXPORT CONTROLS

CBAM Regulation enters transitional phase (Carbon Border Adjustment Mechanism) (see [here](#))

On 1 October 2023, the Carbon Border Adjustment Mechanism (CBAM) Regulation became applicable in its transitional phase ([Regulation \(EU\) 2023/956](#) of 10 May 2023 establishing a carbon border adjustment mechanism).

To recall, CBAM addresses greenhouse gas emissions embedded in imports into the EU of certain products in carbon-intensive industries, in view of ensuring equivalent carbon pricing for imports and domestic products. In this respect, the CBAM seeks to prevent the risk of so-called carbon leakage, which jeopardizes the EU's greenhouse gas emissions reduction efforts when businesses (i) increase emissions outside EU borders by relocating production to non-EU countries with less stringent policies to tackle climate change, or (ii) increase imports of carbon-intensive products.

The Commission emphasizes, in particular, that CBAM will tackle the risk of carbon leakage in a non-discriminatory way and in compliance with WTO rules.

CBAM transitional phase (from 1 October 2023 until 31 December 2025). This phase is to serve as a pilot and learning period for all stakeholders (importers, producers and authorities) and to enable collecting useful information on embedded emissions to refine the methodology for the definitive period.

During the transitional phase, CBAM's scope will only apply to imports of certain goods and selected precursors whose production is carbon-intensive and at greatest risk of carbon leakage, covering these six sectors: (i) iron and steel, (ii) cement, (iii) fertilizers, (iv) aluminium, (v) electricity, and (vi) hydrogen. Indirect emissions will be covered after the transitional period for certain sectors (cement and fertilizers), based on a methodology to be defined.

The rules governing implementation during CBAM's transitional phase are provided in the [Implementing Regulation](#), published on 17 August 2023, which sets out the (i) transitional reporting obligations for EU importers of CBAM goods, and (ii) transitional methodology for calculating embedded emissions released during the production process of CBAM goods (see also [Jones Day EU Emergency Update No. 105 of 31 August 2023](#)).

The Commission is also providing guidance on practical implementation of the new rules, such as:

- A new CBAM transitional registry, available since 1 October 2023, to assist importers with undertaking reporting as part of their CBAM obligations (see [here](#));
- A checklist to assist importers of goods with complying with the new rules. The checklist's steps can also be undertaken by the customs representative or declarant, on behalf of the importer (see [here](#)); and
- E-learning modules offering brief introductions to CBAM for EU importers, customs declarants, and third country operators, including the first sector-specific module on cement (see [here](#)).

CBAM timing / next steps. During the transitional period, CBAM will apply only as a reporting obligation. At the end of each quarter, importers shall report emissions embedded in their goods subject to CBAM, but without

paying a financial adjustment. This will allow time for the final system to be put in place, with a definitive methodology expected by 2026.

Importers will be asked to collect fourth quarter data on emissions embedded in their goods subject CBAM as of 1 October 2023, although their first report need only be submitted by 31 January 2024.

European Commission agrees to expiry of restrictive measures on exports of Ukrainian grain to certain EU Member States (see [here](#))

On 15 September 2023, the European Commission agreed to the expiry of restrictive measures on exports of certain Ukrainian agricultural products to five EU Member States (Bulgaria, Hungary, Poland, Romania, and Slovakia). By way of background on such restrictive measures:

[Support to Ukraine following Russian invasion and resulting surge in certain Ukrainian imports to EU:](#)

To support Ukrainian producers/exporters following Russia's military aggression, the [EU temporarily suspended import duties, quotas, and trade defence measures on Ukrainian exports to the EU](#) from 4 June 2022 until 5 June 2023 (as extended until 4 June 2024 under the Autonomous Trade Measures (ATM) Regulation (Regulation (EU) 2023/1077 on temporary trade-liberalisation measures supplementing trade concessions concerning Ukrainian products, see [here](#))).

This temporary trade liberalization led to a surge in traffic at the Ukraine and EU borders, resulting in saturated storage capacities and logistical chains in the five concerned Member States. These exceptional circumstances impacted the economic viability of local producers those Member States.

Consequently, the Commission adopted [temporary restrictive measures on imports from Ukraine of four agricultural products](#) (wheat, maize, rapeseed, and sunflower seed) from 2 May 2023 to 5 June 2023 (and extended until 15 September 2023, see [here](#)), as implemented under the exceptional safeguard of the above-referred ATM Regulation. These measures, which aimed at alleviating logistical bottlenecks arising from Ukrainian agricultural products in the concerned Member States, were also notably accompanied by the following:

- Bulgaria, Hungary, Poland, and Slovakia committed to lift their unilateral measures on wheat, maize, rapeseed, sunflower seed, and any other products coming from Ukraine.
- A Joint Coordination Platform was established to coordinate the efforts of the Commission, Bulgaria, Hungary, Poland, Romania, Slovakia, and Ukraine to improve the flow of trade between the EU and Ukraine and to increase logistical capacity.

[Assessment leading to expiry of temporary restrictive measures.](#) Following an analysis of data on the impact of the four concerned Ukrainian agricultural products on the EU market, the Commission concluded that market distortions in the concerned Member States had been resolved through the temporary restrictive measures and the Joint Coordination Platform's work.

In turn, Ukraine agreed in particular to introduce legal measures (including, for example, an export licensing system) within 30 days to avoid grain surges. According to press reports, Ukraine proposed an export control plan to the Commission, Poland, Hungary, Slovakia, Bulgaria, and Romania in relation to

four crops (wheat, maize, sunflower, and rapeseed) to protect the domestic markets of those Member States.

Looking ahead. The Commission indicated that it will refrain from imposing any restrictions on Ukraine's exports to the EU, as long as Ukraine's measures are in place and effective.

Nevertheless, Poland, Slovakia, and Hungary announced unilateral restrictions on Ukrainian imports, spurring Ukraine to file a complaint against these three countries before the WTO on 21 September 2023 (see [here](#)).

MEDICINES AND MEDICAL DEVICES

President of European Council speaks at first UN High-Level Meeting on Pandemic Prevention, Preparedness and Response ([here](#))

On 20 September 2023, the United Nations General Assembly held its first-ever High-Level Meeting (HLM) on Pandemic Prevention, Preparedness and Response in New York, focusing on creating and maintaining political momentum and solidarity in these areas.

The President of the European Council, Charles Michel, spoke at the HLM, emphasizing the responsibility of learning from the COVID-19 pandemic, and in particular two clear lessons that (i) such situations must be dealt with together at a global scale; and (ii) better preparedness is needed in order to prevent and anticipate pandemics. In this respect, President Michel raised the following:

- To further global solidarity, he urged to finalize by May 2024 a proposed International Agreement on pandemic prevention, preparedness and response, which is currently under discussion by an inter-governmental negotiating body established by the World Health Assembly. The Agreement would be legally binding under international law.

To recall, this proposed International Agreement, spurred by the COVID-19 pandemic, would seek to strengthen the early detection of pandemics, improve alerts and response, and promote general trust in the international health system. The Council of the European Union had earlier adopted a Decision on 3 March 2022, authorizing the European Commission to represent the EU in the inter-governmental body in charge of developing and negotiating the International Agreement (see also [Jones Day COVID-19 EU Regulatory Update No. 78 of 4 March 2022](#)).

- On intellectual property, President Michel also urged that “*when science rises to the challenge ... in record time to develop vaccines which had a positive impact ... we must make sure that innovations are shared. That is the point, in fact, of the discussions on intellectual property. Progress has been made on a consensus, including on that subject; let us try not to re-open battles which will jeopardise our ability to reach agreements in the coming months on such an important subject.*” (emphasis added)

To recall, at the WTO Twelfth Ministerial Conference (MC12) on 22 June 2022, trade ministers adopted a temporary waiver on IP rights of COVID-19 vaccines (limited to patents) by a [Ministerial Decision](#) on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) (see also [Jones Day COVID-19 EU](#)

[Regulatory Update No. 79 of 16 March 2022](#)). The Ministerial Decision notably:

- Afforded members with broader scope to take direct action to diversify COVID-19 vaccine production and to override the exclusive effect of patents through a targeted temporary waiver over the next five years.
- Provided that members would decide within six months from the Ministerial Decision on the waiver's possible extension to cover the production and supply of COVID-19 diagnostics and therapeutics.

Such potential waiver extension remains under discussion, including at a TRIPS Council [informal session](#) on 28 September 2023, where WTO members met with various external stakeholders on whether to extend the Ministerial Decision to COVID-19 therapeutics and diagnostics.

Finally, at the HLM, world leaders adopted a [Political Declaration](#), calling for stronger international collaboration at the highest political levels to better prevent, prepare for and respond to pandemics. In this broad-ranging document, the General Assembly committed to attaining timely and equitable access to pandemic-related products (e.g., vaccines, diagnostics and therapeutics) timely, calling on the World Health Organization (WHO) to coordinate with relevant partners.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission publishes first report on State of the Digital Decade (see [here](#))

On 27 September 2023, the European Commission published the first Report on the State of the Digital Decade 2023, which assesses the EU's advancements in achieving a successful digital transformation for its citizens, businesses, and the environment, in line with the Digital Decade Policy Programme 2030 ("[Digital Decade Decision](#)" of 19 December 2022, see also [Jones Day COVID-19 Update No. 94 of 19 December 2022](#)).

The Report notes that the COVID-19 pandemic, Russia's war against Ukraine, and other geopolitical risks have highlighted the importance of ensuring the EU's secure and collectively resilient digital transformation. The Digital Decade's concrete objectives and targets (to be achieved by 2030) address these concerns, vulnerabilities, and dependencies of the EU and its Member States.

In particular, the Report provides an overview of:

- The current status of the **digitization of businesses**. It emphasizes that adoption of digital technologies by European companies is still well below the Digital Decade's targets, and in particular concerning the uptake of AI and big data.

In this regard, to ensure the [availability and circulation of data](#), the European Commission has focused on legislative measures such as:

- the [Data Governance Act](#), which establishes a legal framework promoting data sharing, data availability and data reuse (see [here](#) and [Jones Day COVID-19 Update No. 70 of 6 December 2022](#));

- the proposed [Data Act](#), which complements the Data Governance Act by clarifying legal access to and use of data, applicable to both personal and nonpersonal data, and relevant to all companies generating, holding or transferring data in the EU (see [Jones Day COVID-19 Update No. 77 of 23 February 2022](#));
- [European data spaces](#) in strategic economic sectors (e.g., proposed European Health Data Space, see [Jones Day COVID- 19 Update No. 84 of 17 May 2022](#)), which seeks to create a common space in which individuals can easily control their electronic health data and enable researchers, innovators and policymakers to use this electronic data in a trusted and secure way;
- the proposed [Artificial Intelligence Act](#), which aims at boosting the development of AI systems by providing a clear legal framework on the placing on the market, putting into service, and use of AI systems in the EU (see [Jones Day Commentary, Regulating Artificial Intelligence: European Commission Launches Proposals of April 2021](#)).

The Report further recommends that EU Member States undertake, e.g., policy measures and dedicate resources to support AI solutions; the sharing of data by supporting wider deployment/procurement of big data solutions; and stimulating national efforts for cloud adoption through cloud-targeted investment and exploitation strategies for advanced cloud solutions among businesses.

- The **current and volatile cybersecurity landscape**, with a rise in cyberthreats by 150% in a year. The EU has reinforced its legal framework to monitor and prevent cyber-attacks, notably with the [NIS2 Directive](#) of 27 December 2022 and the opening of the European Cyber Security Competence Centre. Still, an urgent need remains to enhance situational awareness, crisis preparedness and response capabilities. For example, the proposed [Cyber Resilience Act](#), which imposes cybersecurity requirements on hardware and software available in the EU, could significantly transform EU efforts to combat such attacks (see [Jones Day COVID-19 Update No. 87 of 23 September 2022](#)).
- The importance of **digitalization in the healthcare sector**. The EU demonstrates strong performance in the field of the access to e-health records and is on its way to achieving the EU target of providing all EU citizens with access to their electronic health records. A notable example of this success are the 2.3 billion EU Digital COVID certificates issued in the EU (see [Jones Day COVID-19 Update No. 95 of 9 January 2023](#)).

In conclusion, the Report highlights that the Digital Decade's success will be of pivotal importance to the EU's future prosperity. However, the EU's digital transformation requires much greater action from the EU and Member States to enhance digital technologies, skills and infrastructures.

Next steps. Within two months after the Report's adoption, the Commission and Member States will discuss preliminary observations, focusing on the Commission's recommendations in the Report.

Data Governance Act becomes applicable (see [here](#))

On 24 September 2023, the Data Governance Act (Regulation (EU) 2022/868 on European data governance) entered into application (see also [Jones Day COVID-19 Update No. 70 of 6 December 2022](#)).

To recall, the proposed Data Governance Act seeks to create a safe environment for sharing data, which is the objective of the 2020 European Strategy for Data (see [here](#)). The establishment of a single market for data aims to guarantee increased access to data, which is particularly important in situations where EU coordinated action is necessary, such as during the COVID-19 crisis.

More specifically, the Data Governance Act provides for rules and safeguards that facilitate the re-use of data (both personal and non-personal) held by public sector bodies by establishing:

- Conditions for re-use of certain categories of protected public sector data, which provide a set of harmonized basic conditions allowing for the re-use of such data (e.g., requirement of non-exclusive re-use of certain publicly-held data). Member States must implement technical measures to guarantee data protection and confidentiality of data in cases of re-use, for instance, through anonymization or pseudonymization.
- Framework for providing data intermediation services. Data intermediaries (e.g., data marketplaces such as the [API-AGRO](#) agricultural data-sharing hub) are subject to rules for serving as trustworthy, neutral third-parties who organize data sharing or pooling within the common European data spaces. In particular, data intermediaries must notify the competent authority of their intention to provide such services. The authority will verify that the notification procedure is non-discriminatory and does not distort competition.
- Framework for establishing a European Data Innovation Board (“EDIB”) to facilitate sharing best practices on data intermediation, data altruism, as well as prioritization of cross-sectoral interoperability standards. The EDIB will consist of representatives from various entities, such as Member State competent authorities, the European Data Protection Board, and the European Data Protection Supervisor.

Looking ahead. The Commission expects the DGA to serve as a powerful catalyst for innovation and job creation. Businesses are expected to benefit from lower costs for acquiring, integrating and processing data. This will promote the development of data-driven products and services, including facilitating evidence-based policies and better solutions to societal challenges such as climate change and pandemics.

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