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Subject:	Council conclusions on COVID-19 lessons learned in health

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Delegations will find in the annex the Council conclusions on COVID-19 lessons learned in health, approved through a written procedure completed on 17 December 2020.

**Council conclusions  
on COVID-19 lessons learned in health**

**Introduction**

The year 2020 has been a year of unprecedented challenges for Member States, the European Union and the entire world. The COVID-19 pandemic is a health crisis that has an unprecedented detrimental impact on our societies and economies. It still remains a Public Health Emergency of International Concern, declared by the World Health Organization (WHO) on 30 January 2020<sup>1</sup>.

While the epidemiological situation is still evolving and is likely to continue to do so, until a large percentage of the world population has acquired immunity, is vaccinated, or can be treated adequately, the European Union, its Member States and its citizens need to prepare for the future. The challenges which we currently face can only be effectively tackled together. This requires close collaboration and coordination between Member States, the institutions of the European Union, civil society and the entire global community.

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<sup>1</sup> [https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov))

Learning lessons from the current crisis and jointly drawing the right consequences are and will be important steps towards a stronger and more resilient European Union. It is a fundamental finding that the outbreak of the COVID-19 pandemic has revealed and exacerbated vulnerabilities in a wide variety of issues and areas. In the area of health, the focus must be on the pandemic preparedness and response of the European Union and its Member States to tackle the ongoing COVID-19 pandemic and future health threats, on ensuring the supply of medicinal products and medical countermeasures in general, improving access to and sharing of health data which is essential to fight this pandemic, as well as other cross-border health threats, and on strengthening the role of the European Union in global health – issues that are partly inseparable. The pandemic also affects the health care services and treatments of other patients, inter alia those with cancer and other non-communicable diseases, due to the impact of measures in place to tackle the pandemic.

It is our responsibility in the European Union to draw the lessons already learned and to emerge stronger and more resilient from this crisis to benefit our citizens and patients. In full respect of their respective competencies, the European Union, its Member States and the European institutions need to jointly enhance their capabilities, both to ensure they can act effectively in the event of health emergencies and to work towards achieving European autonomy in strategic areas while preserving an open economy.

## Lessons learned: Improving EU crisis management

### THE COUNCIL OF THE EUROPEAN UNION

1. RECOGNISES that while health security and pandemic preparedness planning remain primarily a Member State competence, the COVID-19 pandemic has highlighted the added value of and need for solidarity in the form of addressing relevant issues on the European level.
2. RECALLS its conclusions of 13 February 2020 on COVID-19, which called for continued and increased cooperation at Union and international level<sup>2</sup>, REAFFIRMS with reference to the statement of the members of the EU Council of 26 March 2020<sup>3</sup> the need for an enhanced cooperation among Member States during the COVID-19 crisis, including joint efforts to address remaining bottlenecks in deliveries of medical supplies and provide mutual support in treating patients, and APPRECIATES the considerable solidarity and cooperation shown so far.
3. WELCOMES the proposal by the Commission for a stand-alone health programme EU4Health, within the Multiannual Financial Framework 2021-2027 as an instrument to provide Union added value and to complement the policies of the Member States in order to improve human health throughout the Union, in particular to protect people in the European Union from serious cross-border threats to health and supporting the strengthening and the responsiveness of health systems to cope with those threats and taking into account the results of the European Council of 21 July 2020<sup>4</sup>.

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<sup>2</sup> <https://www.consilium.europa.eu/de/meetings/epsco/2020/02/13/>

<sup>3</sup> <https://www.consilium.europa.eu/media/43076/26-vc-euco-statement-en.pdf>

<sup>4</sup> <https://www.consilium.europa.eu/media/45109/210720-euco-final-conclusions-en.pdf>

4. INVITES Member States and the Commission to make use of funding opportunities linked to the COVID-19 pandemic, such as the Recovery and Resilience Facility, the European Regional Development Fund, the European Social Fund+, Invest EU, as well as targeted EU programmes, such as EU4Health, the Digital Europe Programme and Horizon Europe, to support the necessary transformation of health and care, including digital health.
5. TAKES NOTE of the general need to enhance the Union's crisis management and preparedness by strengthening the EU health security framework, including the European Centre for Disease Prevention and Control (ECDC), the Health Security Committee (HSC) and the European Medicines Agency (EMA) and the Integrated Political Crisis Response (IPCR), and HIGHLIGHTS the need to ensure the supply of medical countermeasures in the EU, as well as the need for further expert discussion on the necessary improvements regarding the exchange of comparable health data for the purposes of research, prevention, diagnostics and development of new treatments while complying with data protection rules.
6. STRESSES the importance of the work carried out by the ECDC, especially in providing the best available knowledge, as well as by the HSC and IPCR, and TAKES NOTE of the measures outlined in the Communication on Short-term EU health preparedness for COVID-19 outbreaks<sup>5</sup> and on additional COVID-19 response measures<sup>6</sup>.
7. STRESSES that the development and deployment of rapid and reliable diagnosis, a curative treatment or an effective and safe vaccine are key to coping with the pandemic. Furthermore STRESSES the importance of ensuring fair, equitable, transparent and global access to COVID-19 vaccines and of supporting efforts for a fair and transparent process within the European Union to ensure that COVID-19 vaccines are available for the populations of the EU Member States.

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<sup>5</sup> [https://ec.europa.eu/info/sites/info/files/communication\\_-\\_short-term\\_eu\\_health\\_preparedness.pdf](https://ec.europa.eu/info/sites/info/files/communication_-_short-term_eu_health_preparedness.pdf)

<sup>6</sup> <https://ec.europa.eu/info/sites/info/files/communication-additional-covid-19-response-measures.pdf>

8. IS CONCERNED about the continuing issue of disinformation, especially in connection with the existence of the virus, the use of masks and the development of a vaccine against COVID-19, and ENCOURAGES a more coordinated approach to public communication about health taking into account national competencies and contexts.
9. UNDERLINES the need to further strengthen efficient information exchange on national surveillance measures, and on testing capacities as well as the need to enhance data sharing on agreed indicators with the ECDC, HSC and IPCR in order to continue to improve the coordination of their activities in this field.
10. CALLS UPON Member States and the Commission to cooperate within their respective competences with the aim of facilitating and fostering cross-sectoral information-sharing between Member States and within relevant fora involved in the European Union's crisis management. Such fora are IPCR, the HSC, the Early Warning and Response System (EWRS), and the ECDC. The aim is to avoid duplication of work and to ensure an efficient, effective and joint response to the pandemic by the European Union - also with regard to the cooperation with WHO's Regional Office for Europe.
11. TAKES NOTE of the need for efficient, secure and rapid cross-border contact-tracing procedures in accordance with data security, data protection and privacy rules.

12. CALLS UPON the Commission to assess the need for further effective contact-tracing mechanisms with regard to all modes of transport, aimed at averting serious health threats to EU citizens. This could include the promotion of contact-tracing procedures such as digital passenger locator forms and, in the long term-perspective, a digital single point of entry platform working across all interested Member States for the identification of persons arriving from pandemic risk areas and their place of residence to ensure compliance with testing and quarantine obligations. A digital single point of entry platform could implement an integrated approach to collecting relevant contact data lists and providing competent national health authorities with 24/7 access. The methods of contact-tracing across borders and their impact should be further evaluated. Further consideration is needed to avoid double reporting and administrative burden.
13. INVITES the Commission together with Member States to continue their efforts to build a European reserve of resources and INVITES Member States to share experiences and to coordinate their efforts, where relevant, when building national reserves and stockpiles for crisis-relevant goods to avoid competition.
14. INVITES the Commission to evaluate the situation and report, within the first half of 2021, on the deployment of different mechanisms for emergency support and for the procurement of medical countermeasures such as personal protective equipment (PPE), including the joint procurement procedure (Decision 1082/2013/EU)<sup>7</sup> and the Emergency Support Instrument (Regulation (EU) 2016/369)<sup>8</sup> with respect to, inter alia, governance structure, transparency, information exchange between the Commission and Member States, and interfaces of these instruments and, based thereon, to develop clear, fast and efficient mechanisms for the procurement of medical countermeasures during a crisis which are of additional value to the national structures and procurements.

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<sup>7</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC.

<sup>8</sup> Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID- 19 outbreak.

15. RECALLS the lessons learned of the first wave of the COVID-19 pandemic such as with regard to the difficulties of fast submission of comparable data to ECDC within the surveillance system, the challenge to develop forecasts based on common modelling activities and indicators, the quick translation of changing scientific evidence and knowledge in policy- and action-oriented language, the difficulties to understand different health systems and their respective needs and approaches to crisis management, difficult mutual assistance when multiple Member States are affected and the situation of people living and commuting in border regions and facing different non-pharmaceutical public health measures and border controls that affected their daily life.
16. TAKES NOTE of the legislative proposals for a long-term EU health security framework with a view to strengthening the ECDC, the EMA and health security crisis management through revising Regulation (EC) No 851/2004<sup>9</sup> (ECDC) and Decision 1082/2013/EU<sup>10</sup> and supplementing Regulation 726/2004<sup>11</sup> (EMA).
17. CALLS UPON the Commission and Member States to conduct a Joint After Action Review after the COVID-19 pandemic has been overcome, in order to analyse the actions performed by all EU institutional actors and the need for additional actions to improve the EU's crisis preparedness and ability to respond to future health threats, avoiding duplication with other ongoing reviews. This should also include a study of the effects of the COVID-19 pandemic on public health and on treatment of patients, with communicable or non-communicable diseases such as cancer, and on antimicrobial resistance (AMR).

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<sup>9</sup> doc. 12972/20

<sup>10</sup> doc. 12973/20 + ADD 1

<sup>11</sup> doc. 12971/20



## Lessons learned: Ensuring the supply of medicinal products

### THE COUNCIL OF THE EUROPEAN UNION

18. ACKNOWLEDGES that shortages of medicinal products and the dependency on a limited number of third countries and manufacturing sites for many products, such as active pharmaceutical ingredients (APIs), in the off-patent sector are of major concern, STRESSES the need to secure the EU supply, RECALLS the Council's longstanding call for shortages of medicinal products to be tackled collectively and UNDERLINES the need for evidence-based action to address the threat posed to health care systems by those shortages.
19. RECOGNISES that shortages of medical devices and PPE also constituted a high threat to health care delivery at the beginning of the COVID-19 pandemic and RECALLS that in the future medical devices and in vitro diagnostic medical devices deserve attention.
20. ACKNOWLEDGES that the market for health-related crisis-relevant goods has been under considerable strain during the COVID-19 crisis and that restrictions with a strong impact on the Internal Market have been introduced by Member States, and UNDERLINES the need to make sure that measures implemented because of the crisis do not lead to lasting distortions in the Internal Market.
21. ACKNOWLEDGES that the European Council has highlighted that achieving strategic autonomy while preserving an open economy is a key objective of the Union and INVITES the Commission to follow up, as a priority, on the invitation of the European Council of 1 and 2 October 2020 to identify strategic dependencies, particularly in the most sensitive industrial ecosystems such as for health, and to propose measures to reduce these dependencies, including by diversifying production and supply chains, ensuring strategic stockpiling, and fostering production and investment in Europe<sup>12</sup>.

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<sup>12</sup> <https://www.consilium.europa.eu/media/45910/021020-euco-final-conclusions.pdf>

22. TAKES NOTE of the Pharmaceutical Strategy for Europe<sup>13</sup>, adopted by the Commission and CALLS UPON the Commission to cooperate with the Member States to develop an ambitious implementation agenda with a clear timeline and the necessary long-term financing to implement concrete actions that follow from the Pharmaceutical Strategy for Europe.
23. EXPRESSES CONCERN that some manufacturers may lack competitiveness when producing pharmaceuticals (raw materials, APIs, intermediates, finished products) inside the EU and that this may be due in part to high EU production costs. CALLS upon Member States to stand out as global leaders on environmental and social standards and clean and innovative production, and STRESSES the need for EU APIs and pharmaceutical manufacturers to modernise their industrial base and integrate new, cost-effective, more efficient and environmentally friendly manufacturing methods and technologies. CALLS UPON the Commission to UTILISE its regulatory frameworks and global influence to achieve a level playing field for EU companies.
24. ACKNOWLEDGES that the availability of medicinal products is linked with the quality of APIs and raw materials and RECOGNISES that quality issues and industrial incidents could increase the risk of shortages while diversifying supply chains can help to counterbalance these challenges. Furthermore, the role of manufacturers with regard to the availability and continuous and adequate supply of medicinal products to Member States' markets should be strengthened.

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<sup>13</sup> doc. 13158/20 + ADD 1

25. STRESSES that continuous and safe supply of high quality medicinal products can only be achieved within a medium- to long-term European strategy based on a multidisciplinary approach to health care policy including actions aimed at improving transparency and quality inspections, diversification of supply chains, building strategic reserves at various levels in the supply chain and providing an environment which is conducive to stimulating innovative and clean production –such as of APIs for critical medicinal products – within the EU, including simplified rules and procedures. NOTES that ensuring the affordability of medicinal products and reducing the environmental impact remain important factors to be considered in that context.
26. CONSIDERS that in order to tackle shortages, it is important to increase cooperation and continuous information exchange at Union level, in particular through and within existing fora aimed at addressing shortages of medicinal products, challenges in distribution chains and shortages in manufacturing capacities while at the same time maintaining national reporting systems on availability or shortages of medicinal products; the information exchange includes relevant information on the APIs manufacturing sites submitted by the manufacturing authorisation holder.
27. INVITES the Commission to explore the creation of data management tools and appropriate procedures and to reinforce existing EU level tools in order to collect information on the whole supply chain such as sources of supply, global manufacturing sites for APIs and other pharmaceutical substances. This serves to increase transparency and visibility of both unilateral dependencies and critical manufacturing sites; UNDERLINES that increasing transparency throughout the lifecycle of medicinal products is important, and therefore FURTHER INVITES Member States to share available information and to cooperate, where appropriate, across the product value chain, keeping in mind not to place unnecessary burden on the industry.

28. CALLS UPON Member States and the Commission to jointly work on a list of critical medicinal products (e.g. antimicrobial APIs, APIs for intensive care medicinal products or vaccines) to ensure the European Union's strategic autonomy in the long-term.
29. INVITES the Commission to ensure monitoring of critical medicinal products during potential future health emergencies and to consolidate the mechanisms to prepare for and respond to health crises, including by monitoring and mitigating shortages of medicinal products.
30. UNDERLINES that improved international cooperation by EU competent authorities will enable more efficient inspections and thus ensure continuous API quality.
31. INVITES the Commission to consider strengthening international cooperation by promoting high level standards in global cooperation, such as the guidelines established by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)<sup>14</sup> and encouraging global partners to comply with these standards, and within the framework of Good Manufacturing Practice (GMP) inspections with Mutual Recognition Agreement (MRA) partner states, the European Directorate for the Quality of Medicines and HealthCare (EDQM)<sup>15</sup> and the Pharmaceutical Inspection Co-operation Scheme (PIC/S)<sup>16</sup> authorities, and to assess whether the mutual recognition of official GMP documents for manufacturing sites outside the territory of the issuing authority can also be supported in MRA partner states.
32. NOTES that Member States can adapt national regulations of procurement processes in order to strengthen the resilience of supply for critical medicinal products, while also noting that this is an area of national competence and taking into account the financial sustainability of Member States' health systems.

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<sup>14</sup> <https://www.ich.org/>

<sup>15</sup> <https://www.edqm.eu/>

<sup>16</sup> <https://picscheme.org/en/picscheme>

33. INVITES the Commission to explore possibilities of facilitating the maintenance in the EU and the relocation to the EU of API manufacturing sites for critical medicinal products.
34. INVITES Member States and the Commission to analyse existing and to explore, where appropriate, new incentives and to assess regulatory requirements for critical medicinal products in the EU and to explore mechanisms to adapt these incentives and alleviate these requirements to ensure availability of critical medicinal products while bearing in mind the pharmaceutical industry's role to ensure timely, safe and qualitative supply of affordable medicinal products to Member States' markets and to prevent the withdrawal of old and effective critical medicinal products from the market.
35. INVITES the Commission to explore possibilities to use the EU science hub for research needs in case of public health crisis.

#### **Lessons learned: Improving access to and sharing of health data**

#### **THE COUNCIL OF THE EUROPEAN UNION**

36. ACKNOWLEDGES that one lesson already learned from the crisis is that common rules and infrastructure for data sharing, as proposed as part of the European Health Data Space (EHDS), where data from translational science, clinical trials and health care can inform future research and care, are paramount. The ongoing pandemic provides a direct demonstration of how data will transform health and care. Rapid pooling of and access to COVID-19 data across countries have played a critical role in understanding transmission and infection, identifying drug targets, and understanding disease and vaccine developments.

37. NOTES that the COVID-19 pandemic has demonstrated that aggregated health data can strengthen infectious disease surveillance and initiate joint measures to address communicable and non-communicable diseases, e. g. through common initiatives like the Lean European Open Survey on SARS-CoV-2 (LEOSS) project<sup>17</sup>, and has triggered further cross-border cooperation between interested Member States, such as the interoperability framework for contact tracing and warning applications and the EU gateway server.
38. ACKNOWLEDGES the sensitivity of health data and emphasises the importance that all proposed actions are in full compliance with Union and Member States' privacy and data protection rules, are voluntary in nature and are in line with the division of competences between the Union and the Member States.
39. REALISING that data controllers and processors analysing cross-border health data to fight the COVID-19 pandemic have noted a lack of legal clarity and certainty as regards health data processing, URGES the European Data Protection Board (EDPB) to develop a common understanding of the processing of health data by the data protection supervisory authorities, including the development of guidelines on ethical and legal aspects of health data processing for the purpose of scientific research and CALLS FOR the EDPB to reach a consensus on the application of the General Data Protection Regulation (GDPR)<sup>18</sup> in the health sector.

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<sup>17</sup> <https://leoss.net/>

<sup>18</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

40. WELCOMES the intention of the Commission to support the development of tailored European Codes of Conduct for specific categories of data controllers or processors and processing activities in accordance with Article 40 of the GDPR, and INVITES Member States to cooperate at bilateral and multilateral levels to reduce differences in the interpretation and application of the GDPR in the health sector by exchanging best practices, to enhance data quality and make data findable, accessible, interoperable and reusable, to foster use cases of health data for scientific research and to clarify the differences between sensitive health data and non-personal data, especially open data.
41. AWAITS the report "Assessment of the Member States' rules on health data in the light of the GDPR 2019/2020" commissioned by the Commission and its recommendations based on extensive surveys and five workshops with broad participation by experts, representatives of Member States, data protection supervisory authorities, stakeholders from the health sector and EU institutions and INVITES the Commission to continue the successful exchange of best practices with the Member States through a dedicated expert group on secondary use of health data, involving representatives of bodies dealing with secondary use of health data.
42. RECALLS that the European Council welcomed at its special meeting on the handling of the COVID-19 pandemic on 1 and 2 October 2020 the creation of common European data spaces in strategic sectors, and in particular invited the Commission to give priority to the health data space, SUPPORTS measures aiming at increasing the digital maturity of healthcare systems, the interoperability of infrastructures and the standardisation of health records, to allow the access and exchange of data and information through an EHDS, and NOTES that the European Commission's plans to submit, by the end of 2021, a legal proposal on the EHDS.

43. CALLS upon the Commission, the Member States, and all relevant public and private stakeholders to collaborate in order to deliver a functioning EHDS that strengthens citizens' control over their own personal health data, supports the portability, cybersecurity and interoperability of health data, and contributes to the cross-border use and re-use of health data for better healthcare, better research, and better policy-making and regulatory activities, and NOTES that a working EHDS could strengthen the competitiveness of EU industry, while respecting the ethical dimension of health data use, including in connection with the use of AI in health care.
44. WELCOMES the close cooperation between Member States and the Commission in preparing the Joint Action for the EHDS "Towards the European Health Data Space" so as to ensure continuity in the development of a governance strategy for the secondary use of health data at European level and in facilitating access to and exchange of health data through concrete use-cases, including measures to mitigate the COVID-19 pandemic, and INVITES the Commission to duly consider the governance options developed by the Joint Action when preparing legislative and non-legislative measures in connection with the EHDS, in order to ensure a harmonised approach to health data processing which builds upon Member States' national regulations and principles, as well as upon local conditions, such as existing data infrastructure and national initiatives, and fully respects Member State competences and capacities. For sensitive personal data collected by the public sector, it is essential that the public authorities in Member States maintain control over the use of data to guarantee data security and public trust.



45. ENCOURAGES the Commission to initiate and fund pilot projects on health data exchange in collaboration with national authorities in 2021, to set up an interoperable EHDS infrastructure for secondary use of health data by 2025 at the latest, and to facilitate access to European health data repositories through common rules, instruments and procedures, including the European Reference Network registries, and by further initiating and promoting concrete use-cases of EU added value, such as clinical expert networks for further diseases and conditions, and where European exchange of health data is necessary and appropriate, e. g. for the management of severe COVID-19 cases.
46. RECALLING that lifestyle applications can gather relevant health data, which is not yet accessible for healthcare purposes and for public health measures addressing COVID-19 and other cross-border health threats, INVITES Member States and the Commission to develop a shared European management model for the processing of person-generated health data, to, where appropriate, complement electronic health records based on individual informed consent as well as to establish a network of data sharing platforms accessible across the EU and linked to the EHDS infrastructure to serve as key digital interfaces between members of the General Public and trustworthy data users to collect shared data, based on their informed consent and facilitating access to personal data in line with the GDPR, and generating anonymised and aggregated data from which both, insights to improve scientific understanding, especially of chronic disease prevalence, and practical tools for public health institutes could be derived. These platforms should also inform persons sharing their data about the progress made and insights gained by using their data.
47. URGES Member States and the Commission to join forces in promoting digital- and data-related skills to empower individuals, professionals, companies, public sector entities and decision makers, as well as in reducing digital divides, including differences regarding inter alia coverage, equipment, accessibility and literacy.

48. ENCOURAGES Member States and the Commission to continue supporting the work and coordination of the eHealth Network in its efforts to establish a common strengthened interoperability coordination governance among Member States and National eHealth competence centres, to further implement and to enhance the eHealth Digital Service infrastructure (eHDSI), and also to collaborate with the dedicated expert group on secondary health data use in the EHDS.
49. ENCOURAGES Member States and the Commission to support work under way in the context of a secure and trusted EHDS to develop a governance framework linking relevant authorities and bodies in Member States and at EU level, with the aim of allowing the reuse of data in research and policy, building a digital infrastructure for secondary use of health data, and supporting data-driven international collaboration informed by related pilot project activities.
50. INVITES interested new countries to participate in the EU gateway server for contact tracing and warning mobile applications where this could strengthen Member States' capacity to contain the spread of the pandemic and WELCOMES the intensive efforts undertaken by Member States and the Commission in the eHealth Network to introduce an interoperability framework for contact tracing and warning applications and to set up an EU gateway server, which could become an important tool to demonstrate the value and necessity of cross-border exchange of relevant data in response to the pandemic. Further INVITES Member States, the Commission and the ECDC to work together on better alignment of epidemiological datasets for surveillance.

## Lessons learned: Strengthening the EU's role in global health

### THE COUNCIL OF THE EUROPEAN UNION

51. RECALLS the conclusions adopted by the Council and the Representatives of the Governments of the Member States on the role of the EU in strengthening the WHO as the leading and coordinating authority<sup>19</sup> on global health.
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<sup>19</sup> OJ C 400, 24.11.2020, p.1.