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NOTE

From:	General Secretariat of the Council
To:	Working Party on Public Health
Subject:	Draft Council conclusions on COVID-19 lessons learned in health

Delegations will find enclosed a second revised set of draft Council conclusions on COVID-19 lessons learned in health prepared by the Presidency on the basis of written comments received from delegations after the VTC meeting of the members of the Working Party on Public Health on 13 November 2020.

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Changes to the text in document 11528/1/20 REV 1 are indicated as follows:

Bold italics = new text

~~strikethrough~~ = deleted text

The text that was set out in bold italics in document 11528/1/20 REV 1 is now presented in normal characters and the text that was stricken through is now deleted.

Draft 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. ~~in living memory, causing human tragedy and socio-economic upheaval.~~ It still remains a Public Health Emergency of International Concern, declared by the World Health Organization (WHO) on 30 January 2020¹.

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

¹ [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 ~~the~~ lessons from the **current** crisis and jointly drawing the right consequences **are** is and will be ~~an~~ 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** ~~great~~ 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 ~~either the measures in place to tackle the pandemic or due to the impact of these 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 ~~capacity to~~ **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

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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 ~~by~~ *in the form of* addressing relevant issues on the European level.
2. RECALLS its ~~conclusions~~ ~~Conclusions adopted on~~ of 13 February 2020 on COVID-19, ~~which that~~ called for continued and increased cooperation at Union and international level², REAFFIRMS with regard ~~reference~~ to the *statement of the members of the* EU Council of 26 March 2020³ 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 ~~important signs~~ *of 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 ~~have~~ *provide* Union added value and to complement the policies of the Member States in order to improve human health throughout the Union, ~~Specifically, in particular to~~ protecting 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 2020⁴.
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.*

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

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

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

5. ~~RECALLS~~ **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) as well as **and** the European Medicines Agency (EMA) **and the Integrated Political Crisis Response (IPCR)**, and HIGHLIGHTS the need to ensure the supply of ~~medicinal products~~ **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 ~~in line~~ **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 outbreaks⁵ and on additional COVID-19 response measures⁶.
7. STRESSES that the development and deployment of **rapid and reliable diagnosis**, a curative treatment or an effective and safe vaccine are key to ~~deal~~ **coping** with the pandemic. Furthermore STRESSES the importance of ensuring fair, equitable, transparent and global access to COVID-19 vaccines and ~~to~~ **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.
8. IS CONCERNED about the continuing **issue of** disinformation, especially in ~~view of~~ **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 of the~~ public communication about health **taking into account national competencies and contexts**.

⁵ https://ec.europa.eu/info/sites/info/files/communication_-_short-term_eu_health_preparedness.pdf

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

9. UNDERLINES the need to further strengthen ~~an~~ efficient information exchange on national surveillance measures, *and on* testing capacities ~~and~~, *as well as the need to enhance* data sharing *on agreed indicators* with the ECDC, ~~and~~ HSC *and IPCR* in order to continue to improve the coordination thereof.
10. CALLS UPON Member States and the Commission to cooperate within their respective competences with the aim ~~to~~ *of facilitating* and *fostering* cross-sectoral information-sharing between Member States and within relevant fora involved in the European Union's crisis management. ~~This includes~~ *Such fora are the Integrated Political Crisis Response (IPCR), the Health Security Committee (HSC), the Early Warning and Response System (EWRS), and* the ECDC. The aim is to avoid duplication of work, ~~also with regard to WHO's Regional Office for Europe~~ and to ensure the European Union's *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 ~~to~~ **at averting** serious health threats to ~~the~~ 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 point of entry-platform could implement an integrated approach ~~to in~~ collecting relevant data contact lists and providing 24/7 ~~access to~~ competent national health authorities ~~within~~ **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. regarding the possible use of passenger contact information to fight the pandemic, taking into account possible amendments to Directive (EU) 2016/681 (PNR) and the planned revision of Directive (EC) 2004/82 (API).]~~
13. INVITES the Commission together with Member States to continue their efforts ~~on~~ **to** building a ~~common~~ **European** reserve **of resources** under the EU Civil Protection ~~M~~mechanism, **and INVITES Member States** ~~as well as the 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~~ of emergency support and for the procurement of medical countermeasures such as ***personal protective equipment (PPE)***, including the joint procurement procedure (Decision 1082/2013/EU)⁷ and the Emergency Support Instrument (Regulation (EU) 2016/369)⁸ with respect to, inter alia, governance structure, transparency, information exchange between the Commission and Member States, and interfaces of these instruments ~~within the first half of 2021~~ 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.***
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*** preparedness measures with ***a view*** regard to strengthening the ECDC, the EMA and health security crisis management through ***revising*** ~~reforming~~ Regulation (EC) No 851/2004⁹ (***ECDC***) and Decision 1082/2013/EU¹⁰ and supplementing [;] Regulation 726/2004¹¹ (EMA).

⁷ 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.

⁸ 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.

⁹ ***doc. 12972/20***

¹⁰ ***doc. 12973/20 + ADD 1***

¹¹ ***doc. 12971/20***

~~[1315.ENCOURAGES the Commission in collaboration with and Member States to support ensure the adequate equipment of the ECDC to:~~

- ~~• establish a digital surveillance system in line with data protection rules that is linked with the systems of the Member States to simplify the transmission of comparable data. The ECDC offers assistance to while supporting Member States developing in the development of the national digital surveillance systems;~~
- ~~• enhance modelling and forecasting capacities;~~
- ~~• enhance its activities and cooperation with the partner institutions worldwide including communication and promotion abilities global visibility, cooperation and activities with partner institutions worldwide.]~~
- ~~• make recommendations emitted by ECDC more policy and action oriented;~~
- ~~• establish a permanent Health Task Force in the ECDC composed of several teams with liaison officers for technical support in the field of health security to carry out missions to enhance stronger cooperation on EU level and between countries in times of non-crisis and to support crisis management in case of serious cross-border health threats when multiple Member States are affected and mutual assistance is difficult. This support could be enhanced in light of the results of the different evaluation and after action reviews.]~~

~~[1516.INVITES ENCOURAGES Member States and the Commission to consider to develop a strategies that promoting the coordination of regional and local preparedness plans in cross-border regions, and integrates these in the wider EU crisis management mechanisms with a view to achieve coherent, multi-sectoral, cross-border public health measures, to identify and assure the use of critical infrastructure, to enable cross border contact tracing, to facilitate mutual assistance in hospital care and to develop bilingual, coherent communications concerning all these activities. in a common EU approach to manage areas of active virus circulation and avoid EU internal border closures. The strategy should also take into account Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemics.]~~

17. CALLS UPON the Commission and Member States to conduct a Joint After Action Review after ~~having overcome~~ 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 ~~in additional areas for future~~ ***to*** improvement of ~~the~~ EU's crisis preparedness and ***ability to*** respond ~~se~~ ***to future*** health threats, ***avoiding duplication with other ongoing reviews***. This should also include a study ~~of on~~ 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).

Lessons learned: Ensuring the supply of medicinal products

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18. ACKNOWLEDGES that shortages of medicinal products and the dependency on a limited number of third countries and ~~on a few~~ manufacturing sites for many products, ~~especially~~ ***such as Active Pharmaceutical Ingredients (APIs)***, in the off-patent sector are ~~issues of~~ major concern, STRESSES the need to secure the EU supply, ~~and~~ RECALLS the ***Council's*** longstanding call ~~of the Council to tackle collectively the~~ ***for*** shortages of medicinal products ***to be tackled collectively*** and UNDERLINES the need for ***evidence-based*** action to address the threat posed to ~~the~~ health care systems by those shortages.
19. RECOGNIZES that shortages of medical devices and ***PPE*** ~~personal protective equipment~~ 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 diagnostics ~~medical devices~~ ***deserve a specific attention given their growing interactions with medicinal products*** ~~and the fact that no EU Agency has competences in these fields yet.~~

20. ACKNOWLEDGES that the ~~Single M~~arket 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 ~~Single~~-**Internal** Market have been introduced by Member States, and UNDERLINES the need to make sure that ~~the temporary~~ measures implemented because of the crisis do not lead to **lasting permanent** distortions in the ~~Single~~ **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, ~~with~~ **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, ~~as well as~~ **and** fostering production and investment in Europe¹².

~~[1822. WELCOMES that the Commission has prioritised the issue of continuous and safe supply of medicinal products and incorporates addressed it with concrete measures in their EU Pharmaceutical Strategy for Europe to increase the knowledge and identify the vulnerabilities of the supply chains and ensure preparedness, and resilience and security of supply through a holistic approach from availability to sustainability including availability, accessibility and affordability of medicinal products, in full respect of the principle of subsidiarity.]~~

~~[1923. ASKS the Commission to align objectives concerning “Ensuring availability of medicinal products in the EU” in the EU Pharmaceutical Strategy with the respective objectives in the EU Industrial Strategy, the EU Recovery Plan and the EU Green Deal.]~~

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

22. **TAKES NOTE of the Pharmaceutical Strategy for Europe¹³, adopted by the Commission and CALLS UPON** the Commission to cooperate with the Member States to develop ~~by the end of the first quarter of 2021~~ an ambitious implementation agenda with a clear timeline and the necessary long-term financing to implement ~~the concrete legislative and non-legislative~~ actions that follow from the Pharmaceutical Strategy for Europe. ~~taking into account the following priority topics: continuous and safe supply of medicinal products, unmet medical needs/ orphan legislation, Advanced Therapy Medicinal Products (ATMP).]~~
23. EXPRESSES CONCERN that some manufacturers may lack competitiveness when producing pharmaceuticals (raw materials, APIs, intermediates, finished ~~products dosage forms~~) inside the EU and that this may be *due* in part ~~due~~ to high EU production costs. CALLS upon Member States to stand out *as* globally ~~as leaders~~ on environmental and social standards and clean and innovative production, and STRESSES the need ~~of~~ *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 ~~diversification of~~ *diversifying* supply chains can help to counterbalance these challenges. Furthermore, the ~~responsibility~~ *role* and transparency of manufacturers *with* regarding ~~ing to~~ the availability and continuous *and adequate* supply of medicinal products to *Member States'* the markets should ~~also be~~ *strengthened* ~~considered~~.

¹³ *doc. 13158/20 + ADD 1*

25. STRESSES that continuous and safe supply of high quality medicinal products can only be achieved *within* ~~in~~ a medium- to long-term European strategy based on a multidisciplinary *approach to* health care policy ~~approach~~ including actions aimed ~~to~~ *at* ~~improve~~ *improving* transparency and quality inspections, diversification of supply chains, building strategic reserves at various levels *in the supply chain* and providing an ~~conducive~~ environment *which is conducive* to stimulating innovative and clean production – ~~especially~~ *such as for of APIs of for* critical medicinal products – within the EU, including simplified rules and procedures. NOTES that ~~the environmental impact and~~ *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* transparency of API manufacturing sites deposited in the authorisation documents – ~~especially for API manufacturing – and the continuous information exchange at Union level and thus~~ INVITES Member States and the Commission to strengthen the dialogue and cooperation, in particular through and within existing fora aimed ~~to~~ *at* addressing ~~any~~ 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 at EU level* to collect information ~~to better analyse and understand~~ *on* the whole supply chain *such as* ~~and the sources of supply, and global manufacturing sites for APIs and other pharmaceutical substances. This serves to~~ increase transparency and visibility of both unilateral dependencies and critical manufacturing sites; ~~and~~ UNDERLINES that *increasing* transparency is a broad instrument that can be applied throughout the complete lifecycle of medicinal products *is important*, ~~thus 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~~ MEMBER STATES and the ~~Commission~~ COMMISSION to strengthen collaboration with the European Medical Agency within existing fora 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 ~~and the European Medicines Agency~~ 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** ~~and~~ monitoring and mitigating shortages of medicinal products.
30. UNDERLINES that improved international cooperation ~~on inspections~~ by the EU competent regulatory authorities **regarding inspections** will ensure **enable more efficient and continuous** the API assurance quality ~~more efficiently and continuously~~ and thus;
31. INVITES the Commission to consider strengthening international cooperation by promoting high level standards in global cooperation, ~~for~~ such as **the guidelines established by the** International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)¹⁴ 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)¹⁵ and **the** Pharmaceutical Inspection Co-operation Scheme (PIC/S)¹⁶ 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.

¹⁴ <https://www.ich.org/>

¹⁵ <https://www.edqm.eu/>

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

32. ***NOTES that*** Member States ***can adapt*** to reflect, where appropriate, on the adaptation of 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.*** ~~include as part of their base tender decisions not only on price but also and prioritisation of suppliers a quality assessment with the aim to strengthen the resilience of supply for critical medicinal products while taking into account the sustainability of Member States' health systems.~~
33. INVITES the Commission to explore ~~the all~~ ***possibilities*** of facilitating the maintenance ***in the EU and the relocation to the EU*** of API manufacturing sites for critical medicinal products ~~in to the EU, by adapting and prolonging the “Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak” and INVITES Member States to utilise existing state aid frameworks.~~
34. INVITES Member States and the Commission to analyse existing and ***to*** explore, where appropriate, new ~~financial~~ incentives and to assess ~~administrative hurdles~~ ***regulatory requirements*** for critical medicinal products in the EU and ***to*** explore mechanisms to adapt these incentives and ~~to alleviate these hurdles~~ ***requirements*** to ensure availability of critical medicinal products while ~~not omitting~~ ***bearing in mind*** the pharmaceutical industry's ~~responsibility~~ ***role*** to ensure timely, safe and qualitative supply of affordable medicinal products to the European ***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

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36. ACKNOWLEDGES that a *one* lesson already learned from the crisis is that common rules and infrastructure for data sharing, as proposed *as part of* ~~in~~ 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. Rapidly 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 ~~of~~ 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 activities *measures* to address communicable and non-communicable diseases, e. g. through common initiatives like the Lean European Open Survey on SARS-CoV-2 (LEOSS) project¹⁷, and *has* triggered further cross-border cooperation between interested ~~member~~ *Member* States, ~~health care services~~, such as the interoperability framework for contact tracing and warning ~~A~~applications and the EU gateway server.
38. ACKNOWLEDGES the ~~high~~ 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.

¹⁷ <https://leoss.net/>

39. ~~REALISING~~ that data **controllers and** processors ~~conducting~~ **analysing** cross-border health data ~~analysis~~ to fight the COVID-19 pandemic ~~perceived~~ **have noted** a lack of legal clarity and certainty **as regards** ~~in~~ health data processing, URGES the European Data Protection Board (EDPB) to develop a common understanding ~~of on~~ the processing of health data ~~between~~ **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, ~~notably in the context of the COVID-19 outbreak~~ and CALLS FOR ~~strengthening the role of the EDPB in~~ **to reaching a** consensus on the application of the General Data Protection Regulation (GDPR)¹⁸ in the health sector.
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 ~~a~~ **Article 40** of the GDPR, and INVITES Member States to cooperate ~~on~~ **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~~ **the** 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.

¹⁸ 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).

42. RECALLS that the European Council welcomed ~~in~~ **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*** APPRECIATES ***NOTES*** that the European Commission's ~~foresees~~ ***plans*** to submit, by ~~the~~ end of 2021, a legal proposal on the ***EHDS. European Health Data Space, and*** ~~SUPPORTS the digital maturity of healthcare systems, the interoperability of infrastructures and the standardization of health records, to allow the exchange of data and information through the creation of a European Health Data Space.~~
43. CALLS upon the ~~European~~ Commission, the Member States, and all relevant public and private stakeholders to ~~jointly~~ collaborate in order to deliver a functioning ***EHDS*** ~~European Health Data Space~~ that strengthens citizens' control over their own personal health data, ~~and~~ 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*** ~~European Health Data Space~~ ***can*** ~~could~~ strengthen the competitiveness of EU's industry, while respecting the ethical dimension of health data use, including ~~for~~ ***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*** ~~European Health Data Space~~ "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*** ~~COMMISSION~~ to duly consider the governance options developed by the Joint Action when preparing legislative and non-legislative ~~actions~~ ***measures in connection with*** ~~on the ***EHDS*** European Health Data Space~~, in order to ensure a harmonized 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 ~~for the purpose of~~ ***to guarantee*** data security and ~~citizens'~~ ***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*** ~~European Health Data Space~~ infrastructure for secondary use of health data by ~~latest 2025~~ ***at the latest***, and ***to*** facilitate ~~the~~ 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 ~~EU-wide accessible~~ data sharing platforms **accessible across the EU and** linked to the EHDS infrastructure **to serve** as key digital interfaces between ~~citizens~~ **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** anonymized and aggregated data from which both, ~~scientific~~ insights to improve ~~our~~ **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 ~~that are~~ gained **by using** ~~from~~ their data.
47. URGES Member States and the Commission to join forces in **promoting** ~~strengthening data- and digital- and data-related~~ **skills to empower** ~~competence and building capacity for~~ 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 ~~to~~ and ~~also~~ **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 the work *under way in the context of a secure and trusted EHDS* ~~on the European Health Data Space in the development of~~ *to develop* a governance *framework* linking relevant authorities and bodies in Member States and *at* EU level, with the aim ~~to~~ *of* allowing the reuse of data in research and policy, building a digital infrastructure for secondary use of health data, *and* supporting ~~cross-country~~ data-driven *international* collaboration, informed by related pilot project activities.
50. ~~INVITES Member States and the Commission to encourage~~ *interested* new countries to participate in the EU gateway server for contact tracing and warning mobile applications ~~in order to~~ *where this could* strengthen ~~the~~ *Member States'* capacity ~~of Member States~~ 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 ~~adoption of the~~ *conclusions adopted* by the Council and the Representatives of the ~~g~~ Governments of the Member States on the role of the EU in strengthening the WHO as the leading and coordinating authority¹⁹ ~~in~~ *on* global health.

¹⁹ *OJ C 400, 24.11.2020, p.1.*