



Council of the
European Union

Brussels, 11 November 2020
(OR. en)

11528/1/20
REV 1

LIMITE

SAN 344
PHARM 43
MI 404
IPCR 31
COVID-19 3

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 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. This text is intended for discussion at the informal videoconference of the members of the Working Party on Public Health on 13 November 2020.

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

Bold italics = new text.

~~strikethrough~~ = deleted text.

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

Square brackets are used when the Council Conclusions refer to forthcoming Commission proposals or meetings that have not yet taken place.

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 ~~the worst~~ **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 the epidemiological situation is still evolving and **likely** will so be, until a high percentage of the world population 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 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 crisis and jointly drawing the right consequences is and will be an important step 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 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, ***improving access to and sharing of the use 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 patients, ***inter alia*** in particular 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***.

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 European Institutions need to jointly enhance their capabilities to ensure the capacity to act effectively in the event of health emergencies and to work towards achieving the European autonomy in strategic areas ***while preserving an open economy. – Acting together. Towards European Health Sovereignty.***

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 highlighted the added value of and need for solidarity by addressing relevant issues on the European level.***
12. RECALLS its Conclusions adopted on 13 February 2020 on COVID-19 that call for continued and increased cooperation at Union and international level², ~~and WELCOMES~~ ***REAFFIRMS with regard to the EU Council of 26 March 2020³ the need for solidarity and an enhanced cooperation among Member States during the COVID-19 crises, including joint efforts to address remaining bottlenecks in deliveries of medical supplies and provide mutual support in treating patients, and APPRECIATES important signs of solidarity and cooperation shown so far.***
23. 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 a Union added value and to complement the policies of the Member States in order to improve human health throughout the Union. Specifically, protecting people in the European Union from serious cross-border threats to health and strengthening the responsiveness of health systems to cope with those threats*** ~~support projects with a clear added value in both crisis management and health~~ and taking into account the results of the European Council of 21 July 2020.

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

³ ***reference***

34. RECALLS the **general** need to enhance the Union crisis management and preparedness by strengthening the EU health security framework, **including** ~~and~~ the European Centre for Disease Prevention and Control (ECDC), **the Health Security Committee (HSC)** as well as the European Medicines Agency (EMA), and **HIGHLIGHTS** the need to ensure the supply of medicinal products in the EU, as well as the need for improvements regarding the exchange of **comparable** health data for the purposes of research, **prevention**, diagnostics and development of new treatments **in line with data protection rules**.
45. 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 TAKES NOTE of the measures outlined in the Communication on Short-term EU health preparedness for COVID-19 outbreaks⁴ **and on additional COVID-19 response measures**⁵.
- ~~5. TAKES NOTE of the discussions on contact tracing for cross border travel held at the virtual meeting of Chief Medical Officers on 29 September 2020, in particular on the need for an integrated approach in gathering data for contact tracing in accordance with data security, data protection and privacy rules, and for the establishment of a digital single point of entry platform in the long term perspective.~~
6. STRESSES that the development and deployment of **a curative treatment or** an effective and safe vaccine **are** is key to ~~achieve a permanent solution to~~ **deal with** the pandemic. Furthermore STRESSES the importance of ensuring fair, equitable, transparent and global access to COVID-19 vaccines and to support efforts for a fair and transparent process within the **European** Union to ensure that **COVID-19 vaccines are available for the population of** the EU Member States ~~receive a share that corresponds to their population size~~.

⁴ https://ec.europa.eu/info/sites/info/files/communication_-_short-term_eu_health_preparedness.pdf

⁵ <https://ec.europa.eu/info/sites/info/files/communication-additional-covid-19-response-measures.pdf>

7. ***IS CONCERNED about the continuing disinformation especially in view of the development of a vaccine against COVID-19, and ENCOURAGES a more coordinated approach of the public communication about health.***
78. UNDERLINES the need to further strengthen ***an efficient information exchange on*** national surveillance measures ~~of the occurrence of COVID-19 infections~~, testing capacities ~~and~~, data sharing ~~and close cooperation with the ECDC and HSC to ensure prompt and efficient information exchange as well as~~ ***in order*** to continue to improve the coordination thereof.
89. CALLS UPON Member States and the Commission to cooperate within their respective competences with the aim to facilitate and foster the cross-sectoral information sharing between Member States and within relevant fora involved in the European Union's crisis management. ~~;~~ ***This includes*** ~~ing~~ the Integrated Political Crisis Response (IPCR), the Health Security Committee (HSC), the Early Warning and Response System (EWRS), ~~and~~ the ECDC. ~~;~~ ***The aim is in order*** to avoid duplication of work, ***also with regard to WHO's Regional Office for Europe*** and to ensure the European Union's efficient, effective and joint response to the pandemic.
10. ***TAKES NOTE of the need for efficient and rapid cross-border contact tracing procedures in accordance with data security, data protection and privacy rules.***

911. CALLS UPON the Commission to assess the need for further effective **contact-tracing** mechanisms **with regard to all modes of transport** aimed to avert serious health threats to the EU citizens. This ~~sh~~could include the promotion of contact tracing ~~applications~~ **procedures** such as **digital passenger locator forms** ~~the establishment of a~~ **and in the long term perspective a** digital single point of entry platform working across all Member States ~~modes of transport as well as uniform passenger locator forms~~ 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 in collecting relevant data contact lists and providing 24/7 access to competent national health authorities. The methods of contact-tracing across borders should be further evaluated.** [Further consideration is needed 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).]

1012. INVITES **the Commission together with** Member States **to continue their efforts on building a common reserve under the EU Civil Protection mechanism, as well as the Member States** to coordinate their efforts when building national reserves and stockpiles for crisis relevant goods ~~in full coherence with ongoing work under the EU Civil Protection Mechanism.~~

13. INVITES the Commission to evaluate the situation and report on the deployment of different mechanisms of emergency support and for the procurement of medical countermeasures *such as PPE* including the joint procurement procedure (Decision 1082/2013/EU)⁶ and the Emergency Support Instrument (Regulation (EU) 2016/369)⁷ 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 countermeasure during a crisis.]

14. ~~WELCOMES TAKES NOTE of the legislative proposals for long-term EU health preparedness measures with regard to strengthening the ECDC, the EMA and health security crisis management through reforming Regulation (EC) No 851/2004 , Regulation 726/2004 (EMA) and Decision 1082/2013/EU.] the Communication from the Commission to the Parliament, the Council, the Economic and Social Committee and the Committee of the Regions from [date] on “Lessons learned and Long-term EU Pandemic Preparedness Package” and the legislative proposals for long-term EU health preparedness measures with regard to strengthening the ECDC, the EMA and health security crisis management through reforming Regulation (EC) No 851/2004⁸, Regulation 726/2004 (EMA) and Decision 1082/2013/EU⁹.]~~

⁶ 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.

⁷ 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.

⁸ ~~Regulation (EC) No 851/2004⁸ of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control.~~

⁹ ~~Decision 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.~~

[13]15. 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.]*

14. INVITES the Commission and Member States to consider to establish a permanent Health Task Force in the ECDC for technical support in the field of health security to both Member States and third countries. In order to allow for multiple ECDC teams deployed simultaneously this requires ten teams. The Health Task Force's prime task would be to carry out missions in Member States or third countries to support emerging preparedness and response planning and implementation with regard to best practice, stronger cooperation on EU level and between countries and to support crisis management in case of serious cross-border health threats that affect multiple Member States and where mutual assistance is difficult to carry out.

[1516. INVITES **ENCOURAGES** Member States and the Commission to consider **to develop** a strategy ~~ies that promotes~~**ing** 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.]~~

1617. CALLS UPON the Commission **and Member States** to conduct a Joint After Action Review after having overcome the COVID-19 pandemic to analyse the actions performed **by all actors** and the need for actions in additional areas for future improvement of EU crisis preparedness and response to health threats. This should also include a study on the effects of the COVID-19 pandemic on **public** health ~~care~~ and treatment of patients, ~~in particular those with cancer and other~~ **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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~~1718.~~ ACKNOWLEDGES that shortages of medicinal products and ~~Active Pharmaceutical Ingredients (API) in the off-patent sector~~ and the dependency on ~~third countries~~ *a limited number of third countries* and on a few manufacturing sites for many products *especially Active Pharmaceutical Ingredients (API) in the off-patent sector* are issues of major concern, *STRESSES the need to secure the EU supply and RECALLS the longstanding call of the Council to tackle collectively the shortages of medicinal products* and UNDERLINES the need for action to address the threat posed to the health care systems by those shortages.

19. *RECOGNIZES that shortages of medical devices and 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 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 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 Single 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 permanent distortions in the Single Market.*

21. ***ACKNOWLEDGES that the European Council 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 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 fostering production and investment in Europe¹⁰.***

[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.]

24. ***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).***]

¹⁰ European Council Conclusions on 1 and 2 October 2020

2025. RECOGNISES **EXPRESSES CONCERN** that ~~many~~ **some** manufacturers **may** lack competitiveness when producing their pharmaceuticals (raw materials, **API, intermediates, finished dosage forms**) inside the EU and that this is **may be** in part due to ~~third countries not implementing comparable~~ **high EU production costs. environmental and social standards in the production process and at the same time** RECOGNISES that in order to maintain the competitive advantage, the **CALLS upon Member States to stand out globally as leading on environmental and social standards and clean and innovative production and STRESSES the need of** EU API and pharmaceutical manufacturers ~~need~~ to modernise their industrial base and integrate new, 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.**

2126. ACKNOWLEDGES that the availability of medicinal products is ~~essentially~~ linked with the quality of API and raw materials and RECOGNISES that quality issues and industrial ~~accidents~~ **incidents could** increase the risk of shortages while diversification of supply chains **can** helps to counterbalance these challenges. **Furthermore, the responsibility and transparency of manufacturers regarding the availability and continuous supply of medicinal products to the market should also be considered.**

2227. STRESSES that continuous and safe supply of **high quality** medicinal products can only be achieved in a medium to long-term **European** strategy based on a multidisciplinary health care policy approach including actions aimed to improve transparency and quality inspections, diversification of supply chains, **building strategic reserves at various level and providing a conducive environment to stimulate innovative and clean production – especially for API of critical medicinal products – within the EU, including simplified rules and procedures.** ~~providing financial incentives for maintaining, building and relocating API manufacturing sites in the EU.~~ **NOTES that the environmental impact and affordability of medicinal products remain important factors to be considered in that context.**

2328. CONSIDERS that it is important to increase 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 address 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.

2429. INVITES the Commission to explore the creation of data management tools *and appropriate procedures and reinforce existing tools* at EU level to collect information to better *analyse and* understand the whole ~~supply manufacturing~~ chain and the sources of supply and global manufacturing sites for API to increase transparency and visibility of both unilateral dependencies and *critical important* manufacturing sites *and UNDERLINES that transparency is a broad instrument that can be applied throughout the complete lifecycle of medicinal products, thus FURTHER INVITES Member States to share available information and to cooperate across the product value chain.*

30. *CALLS UPON MEMBER STATES and the 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.*

31. *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 and monitoring and mitigating shortages of medicinal products.*

2532. UNDERLINES that improved international cooperation on inspections by the EU competent regulatory authorities will ensure the API quality more efficiently and continuously and thus;

2633. INVITES the Commission to consider strengthening international cooperation ***by promoting high level standards in global cooperation for such as International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) 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) and Pharmaceutical Inspection Co-operation Scheme (PIC/S)-authorities and 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.

2734. INVITES Member States to reflect, ***where appropriate,*** on the adaptation of national regulations of procurement processes, in order to ***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.*** ~~with supply reliability as well as production diversification and to utilise state aid frameworks to incentivise the relocation of API manufacture to the EU, especially for critical medicinal products while respecting relevant EU legislation on state aid and procurement in order to strengthen the resilience of supply for critical medicinal products.~~

2835. INVITES the Commission to explore the possibility of facilitating the maintenance and relocation 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.***

2936. INVITES Member States and the Commission to ~~review~~ ***analyse*** existing ***and explore where appropriate new*** financial incentives ***and to assess administrative hurdles*** for critical medicinal products in the EU and explore mechanisms to adapt these incentives ***and to alleviate these hurdles*** to ensure availability of critical medicinal products while not omitting the pharmaceutical industry's responsibility to ensure timely, safe and qualitative supply of ***affordable*** medicinal products to the European market.

~~30. CALLS UPON the Commission to utilise its regulatory frameworks and global influence to achieve a level playing field for EU companies.~~

Lessons learned: Improving access to and sharing of health data

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37. ***ACKNOWLEDGES that a lesson already learned from the crisis is that common rules and infrastructure for data sharing, as proposed in the European Health Data Space, 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 and access to COVID-19 data across countries have played a critical role in understanding transmission and infection, identifying drug targets, understanding of disease and vaccine developments.***
- ~~34~~38. NOTES that the COVID-19 pandemic brought the need for easier and more efficient processing of health data, demonstrated that aggregated health data can strengthen infectious disease surveillance and initiate joint activities to address communicable and non-communicable diseases, e. g. through common initiatives like the Lean European Open Survey on SARS-CoV-2 (LEOSS) project, and triggered ~~an urgent need for establishing~~ further cross-border cooperation between ***interested member States***, ~~health care services~~, such as the interoperability framework for contact tracing and warning Applications and the EU gateway server.
- ~~32~~39. ***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 in line with the division of competences between the Union and the Member States.***

40. ***REALIZING that data processors conducting cross-border health data analysis to fight the COVID-19 pandemic perceived a lack of legal clarity and certainty in health data processing, SUPPORTS URGES*** ~~the ongoing activities of the European Data Protection Board (EDPB) in facilitating~~ ***to develop*** a common understanding on the processing of health data between 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 reaching consensus on the application of the General Data Protection Regulation (GDPR)¹¹ in the health sector.
41. ***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 on bilateral and multilateral level to reduce differences in the interpretation and application of the GDPR 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.***

¹¹ 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).

3442. ~~WELCOMES~~ ***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 the recommendations based on extensive surveys and five workshops ~~conducted between January and June 2020~~, 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.

43. ***RECALLS that the European Council welcomed in 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, APPRECIATES that the European Commission foresees to submit by end of 2021 a legal proposal on the 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.***
44. ***CALLS upon the European Commission, the Member States, and all relevant public and private stakeholders to jointly collaborate in order to deliver a functioning European Health Data Space that strengthens citizens’ control over their own personal health data and support the portability and interoperability of health data, 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 European Health Data Space can strengthen the competitiveness of EU’s industry, while respecting the ethical dimension of health data use, including for the use of AI in health care. STRONGLY SUPPORTS the approach of creating a European Health Data Space to strengthen the use and re-use of health data for healthcare, research and innovation, to support health authorities and regulatory bodies in evidence-based decision making, and to contribute to the competitiveness of the EU’s industry, to support the free movement of digital health services and support the development of a framework for AI in health.***

3645. WELCOMES the close cooperation between Member States and the Commission in preparing the Joint Action for the European Health Data Space "Towards the European Health Data Space", as to ensure continuity in the development of a governance strategy for the secondary use of health data at European level and 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 actions on the 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 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 data security and citizens' trust.***

~~37. ENCOURAGES the Commission and Member States to identify legislative and non-legislative actions to support the European Health Data Space, complementing the horizontal framework on common data spaces and taking into account governance options developed by the future Joint Action for the European Health Data Space "Towards the European Health Data Space", in order to ensure a harmonized approach to health data processing, in accordance with Member State competences.~~

~~38. INVITES Member States to cooperate on bilateral and multilateral level to reduce differences in the interpretation and application of the GDPR by exchanging best practices, to enhance data quality and make data findable, accessible, interoperable and reusable, and to foster use cases of health data for scientific research.~~

~~39. INVITES Member States and the Commission to support through their respective funding instruments 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 in order to increase legal certainty and facilitate GDPR-compliant secondary data use within the European Health Data Space.~~

46. 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, European Regional Development Funds, European Social Funds+, Invest EU, but also targeted EU programmes, such as EU4Health, Digital Europe Programme, Horizon Europe, to support the digital transformation of health and care.

~~4047.~~ 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 European Health Data Space infrastructure for secondary use of health data by latest 2025, and*** 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, where European exchange of health data is necessary and appropriate, e. g. for the management of severe COVID-19 cases.

4148. **RECALLING** that lifestyle applications 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, ~~CALLS UPON INVITES~~ Member States and the Commission to develop a shared European management model for processing of person-generated health data, ~~e. g. through lifestyle applications~~, to complement electronic health records based on individual consent (“data solidarity”), ~~including the development of common consent templates; and to establish clear cross-border rules for business-to-business (B2B) and business-to-government (B2G) data access and sharing.~~ **as well as to establish a network of EU-wide accessible data sharing platforms linked to the EHDS infrastructure as key digital interfaces between citizens and trustworthy data users to collect shared data, based on their consent and facilitating access to personal data in line with the GDPR, and anonymized and aggregated data from which both, scientific insights to improve our 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 and insights that are gained from their data.**

4249. **URGES** Member States and the Commission to join forces in strengthening data- and digital-related 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.**

4450. **ENCOURAGES** Member States and the Commission to **continue supporting the work and coordination of** ~~further strengthen the eHealth Network through supporting in its work and coordination to continue the efforts to establishing 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) **also to collaborate with the dedicated expert group on secondary health data use** ~~with new Member States and new use cases to support cross border health care and cross border exchange of data to fight cross-border health threats, and develop respective scalable interoperability modules to be applied in the European Health Data Space.~~

51. ENCOURAGES Member States and the Commission to support the work on the European Health Data Space in the development of a governance linking relevant authorities and bodies in Member States and EU level, with the aim to allow the reuse of data in research and policy, building a digital infrastructure for secondary use of health data, supporting cross-country data driven collaboration, informed by related pilot project activities.

4552. INVITES Member States and the Commission to encourage new countries to participate in the EU gateway server for contact tracing and warning mobile applications *in order to strengthen the 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 Aapplications 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 health data in response to the pandemic.

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

THE COUNCIL OF THE EUROPEAN UNION

[4653. ~~WELCOMES and REAFFIRMS~~ **RECALLS** the adoption of the Conclusions 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 in global health ~~and ENCOURAGES Member States to work jointly towards reforming and strengthening the WHO.]~~