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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 draft Council Conclusions on COVID-19 lessons learned in health developed by the Presidency in the Annex to this Note. These draft Conclusions will be the subject of the elaborations at the informal videoconference of the members of the Working Party on Public Health on 29 October 2020.

ANNEX

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 health crisis 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 Organisation (WHO) on 30 January 2020[1].

Being aware that the epidemiological situation is still evolving and will so be, until a high percentage of the world population is vaccinated, 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)

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, the use of health data, 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, in particular those with cancer and other non-communicable diseases. It is our responsibility in the European Union to draw the lessons learned and to emerge stronger and more resilient from this crisis. 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: **Acting together. Towards European Health Sovereignty.**

Lessons learned: Improving EU crisis management

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1. RECALLS its Conclusions adopted on 13 February 2020 on COVID-19 that call for continued and increased cooperation at Union and international level[2] and WELCOMES solidarity and 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.

2. WELCOMES the proposal by the Commission for a stand-alone health programme EU4Health within the Multiannual Financial Framework 2021-2027 as an instrument to 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.

3. RECALLS the need to enhance the Union crisis management and preparedness by strengthening the EU health security framework and the European Centre for Disease Prevention and Control (ECDC) as well as the European Medicines Agency (EMA), and the need to ensure the supply of medicinal products in the EU, as well as the need for improvements regarding the exchange of health data for the purposes of research, diagnostics and development of new treatments.

4. STRESSES the importance of the work carried out by the ECDC and TAKES NOTE of the measures outlined in the Communication on Short-term EU health preparedness for COVID-19 outbreaks[3].

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

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

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 an effective and safe vaccine is key to achieve a permanent solution to 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 Union to ensure that the EU Member States receive a share that corresponds to their population size.

7. UNDERLINES the need to further strengthen national surveillance measures of the occurrence of COVID-19 infections, testing capacities, data sharing and close cooperation with the ECDC to ensure prompt and efficient information exchange as well as to continue to improve the coordination thereof.

8. 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, including the Integrated Political Crisis Response (IPCR), the Health Security Committee (HSC), the Early Warning and Response System (EWRS) and the ECDC, in order to avoid duplication of work and to ensure the European Union's efficient, effective and joint response to the pandemic.

9. CALLS UPON the Commission to assess the need for further effective mechanisms aimed to avert serious health threats to the EU citizens. This should include the promotion of contact tracing applications such as the establishment of 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. 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).

10. INVITES 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.

11. 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 including the joint procurement procedure (Decision 1082/2013/EU)[4] and the Emergency Support Instrument (Regulation (EU) 2016/369)[5] 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.]

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4 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.

5 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.

[12. WELCOMES 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 851/2004[6], Regulation 726/2004 (EMA) and Decision 1082/2013/EU[7].]

[13. ENCOURAGES the Commission and Member States to ensure the adequate equipment of the ECDC to:

- establish a digital surveillance system that is linked with the systems of the Member States to simplify the transmission of comparable data while supporting Member States in the development of the national digital surveillance systems;
- enhance modelling and forecasting capacities;
- enhance its global visibility, cooperation and activities with partner institutions worldwide.]

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.

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[6] Regulation (EC) No 851/2004[6] of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control.

[7] 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.

[15. INVITES Member States and the Commission to consider a strategy that promotes 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 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.]

16. CALLS UPON the Commission to conduct a Joint After Action Review after having overcome the COVID-19 pandemic to analyse the actions performed 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 health care and treatment of patients, in particular those with cancer and other non-communicable diseases.

Lessons learned: Ensuring the supply of medicinal products

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17. ACKNOWLEDGES that shortages of medicinal products and Active Pharmaceutical Ingredients (API) in the off-patent sector and the dependency on third countries and on a few manufacturing sites for many products are issues of major concern and UNDERLINES the need for action to address the threat posed to the health care systems by those shortages.

[18. WELCOMES that the Commission has prioritised the issue of continuous and safe supply of medicinal products and addresses it with concrete measures in their EU Pharmaceutical Strategy to ensure preparedness and resilience and a holistic approach from availability to sustainability.]

[19. 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.]

20. RECOGNISES that many manufacturers lack competitiveness when producing their pharmaceutical raw materials inside the EU and that this is in part due to third countries not implementing comparable EU environmental and social standards in the production process and at the same time RECOGNISES that in order to maintain the competitive advantage, the EU API and pharmaceutical manufacturers need to modernise the industrial base and integrate new more efficient manufacturing methods.

21. 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 increase the risk of shortages while diversification of supply chains helps to counterbalance these challenges

22. STRESSES that continuous and safe supply of medicinal products can only be achieved in a medium to long-term strategy based on a multidisciplinary health care policy approach including actions aimed to improve transparency and quality inspections, diversification of supply chains and providing financial incentives for maintaining, building and relocating API manufacturing sites in the EU.

23. CONSIDERS that it is important to increase transparency of API manufacturing sites 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.

24. INVITES the Commission to explore the creation of data management tools at EU level to collect information to better understand the whole manufacturing chain and the sources of supply and global manufacturing sites for API to increase transparency and visibility of both unilateral dependencies and important manufacturing sites.

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

26. INVITES the Commission to consider strengthening international cooperation 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.

27. INVITES Member States to reflect on the adaptation of national regulations of procurement processes, in order to base tender decisions not only on price but also prioritise suppliers with the highest standards of quality together 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.

28. INVITES the Commission to explore the possibility of facilitating the maintenance and relocation of API manufacturing sites for critical medicinal products in the EU, by adapting and prolonging the "Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak".

29. INVITES Member States and the Commission to review existing financial incentives for critical medicinal products in the EU and explore mechanisms to adapt these incentives to ensure availability of critical medicinal products while not omitting the pharmaceutical industry's responsibility to ensure timely, safe and qualitative supply of 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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31. 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 health care services, such as the interoperability framework for contact tracing and warning Applications and the EU gateway server.

32. ACKNOWLEDGES the high sensitivity of health data and emphasises the importance that all proposed actions are in full compliance with privacy and data protection rules.

33. SUPPORTS the ongoing activities of the European Data Protection Board (EDPB) in facilitating a common understanding on the processing of health data between the data protection supervisory authorities, including the development of guidelines on 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)[8] in the health sector.

34. WELCOMES 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.

35. 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.

36. 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.

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8 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).

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.

40. ENCOURAGES the Commission 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, where European exchange of health data is necessary and appropriate, e. g. for the management of severe COVID-19 cases.

41. CALLS UPON 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.

42. INVITES Member States and the Commission to establish a network of EU-wide accessible data donation/solidarity platforms linked to the EHDS infrastructure as key digital interfaces between citizens and trustworthy data users to collect donors 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 data donors about the progress and insights that are gained from their data.

43. 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.

44. ENCOURAGES Member States and the Commission to further strengthen the eHealth Network through supporting 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 and also to enhance the eHealth Digital Service infrastructure (eHDSI) 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.

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

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

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[46. WELCOMES and REAFFIRMS 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.]