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From: Mr Wojciech Rafal WIEWIOROWSKI, European Data Protection Supervisor

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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

Subject: Formal comments of the European Data Protection Supervisor on the Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

Delegations will find attached a letter and its annex, signed by Mr Wiewiorowski on the above.



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Brussels, 04 March 2021
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Subject: Formal Comments¹ of the European Data Protection Supervisor on the Regulation of the Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

Your Excellency,
Mr Secretary-General,

Having regard to Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, please find enclosed Formal Comments on the Regulation of the Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

We have sent a copy of these Formal Comments to the President of the European Commission and the President of the European Parliament.

Yours sincerely,

Wojciech Rafał WIEWIÓROWSKI
(e-signed)

Encl.: Formal Comments

Cc: Mr Ralph KAESSNER, Secretariat General of the Council

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¹ Article 20(1) of the EDPS Rules of Procedure provide that "In response to requests from the Commission pursuant to Article 42(1) of the Regulation, the EDPS shall issue opinions or formal comments."

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EDPS Formal comments on the Commission proposal for a Regulation of the Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

1. Introduction and background to the Proposal

- In its Proposal, the European Commission **aims to approximate the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products**, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises.
- The **specific objectives of the Proposal** are to: 1) monitor and mitigate potential and actual shortages of medicinal products and medical devices considered as critical in order to address a given public health emergency or, for medicinal products, other major events which may have a serious impact on public health; 2) ensure timely development of high quality, safe and efficacious medicinal products with a particular focus on addressing a given public health emergency; and 3) ensure smooth functioning of expert panels for the assessment of some high-risk medical devices and avail of essential advice in crisis preparedness and management with regard to the use of medical devices.
- In particular, the Proposal provides that, in order to improve crisis preparedness and management for medicinal products and medical devices and increase resilience and solidarity across the Union, **the procedures and the respective roles and obligations of different concerned entities involved should be clarified.**
- **With respect to medicinal products**, the Proposal plans the establishment of an **Executive Steering Group on Shortages and Safety of Medicinal Products** within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union. Moreover, the Proposal establishes the **creation of an Emergency Task Force**, to provide advice on scientific questions related to the development of treatments and vaccines and on clinical trial protocols, to those organisations involved in their development¹. **With respect to medical devices**, the Proposal plans to **create an Executive Steering Group on Medical Devices** to coordinate urgent actions within the Union in relation to the management of supply and demand issues of medical devices, and to establish a list of critical devices in the case of a public health emergency.
- Lastly, the Proposal aims at **establishing and managing IT infrastructures and synergies with other existing IT systems or systems** under development, including the EUDAMED IT platform for medical devices. The Proposal aims at rapid access and exchange of health data, including real world data (i.e. health data generated outside of clinical studies). Moreover, **the Proposal plans to allow the European Medicines Agency ('EMA') to use and facilitate such exchange and be part of the**

¹ Such as marketing authorisation holders, clinical trial sponsors, public health bodies, and academia, irrespective of their exact role in the development of such medicinal products.

establishment and operation of the European Health Data Space ('EHDS') infrastructure.

- The European Commission has presented the Proposal in conjunction with two other proposals, namely a Proposal for a Regulation on serious cross-border threats to health² and a Proposal to extend the mandate of the European Centre for Disease Prevention and Control ('ECDC')³, with the aim of improving EU-level protection, prevention, preparedness and response against human health hazards.
- These comments are issued pursuant to Article 42(1) Regulation (EU) 2018/1725⁴ ('EUDPR'), following a request for consultation from the European Commission of 11 January 2021. We note that a draft version of the Proposal was submitted to the EDPS in November 2020, to which we have provided informal advice. We limited our comments below to the provisions of the Proposal that are relevant from a data protection perspective.

2. EDPS comments

2.1 General comments

- **The EDPS welcomes the Proposal's general aim to ensure a high level of human health protection by strengthening the Union's ability to manage and respond to public health emergencies**, with an impact on medicinal products and medical devices and to contribute to ensuring the smooth functioning of the internal market for such products during public health emergencies.
- The EDPS notes that Article 30(1)(a) provides that "(...) parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect (...) personal data in accordance with Article 32 (...)". However, as we also note that Article 32 is not present in the Proposal, **we suggest to refer to the protection of personal data in accordance with the definitions contained in Article 4(1) of Regulation (EU) 2016/679 ('GDPR')⁵ and Article 3(1) EUDPR.**
- More generally, the **EDPS notes the lack of a basic provision on the applicability of data protection law**. In this regard, we recommend adding a recital underlining the applicability of the GDPR and EUDPR, and the respect of the principles relating to the processing of personal data (as per Article 5 GDPR and 4 EUDPR).
- The EDPS also notes that the Proposal does not mention the role, within the meaning of data protection law, of EMA, the Commission, Member States and the various bodies

² Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU, COM(2020) 727, final 2020/0322 (COD).

³ Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, COM(2020) 726 final, 2020/0320 (COD).

⁴ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018.

⁵ 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), OJ L 119, 4.5.2016.

to be established. While we are aware that this may not be particularly feasible at present due to the Proposal's nature, **we recommend to specify** (either through a recital or in Article) **that further implementing acts will outline the roles of the actors involved in the processing of personal data through the IT tools and the systems that will be put in place.** In this regard, the EDPS recalls the legal obligation under Article 42(2) EUDPR to be consulted when such legislative proposals will be made.

2.2 Processing of 'electronic health data outside of clinical studies' and 'real-time data'

- Pursuant to Article 15(6)⁶ and Article 16(2)⁷ of the Proposal, the Emergency Task Force will have access to health data processed within clinical trials as well as health data contained in observational studies generated outside clinical studies. **The EDPS draws attention to the sensitive nature of this data and suggests that the Proposal specifies that a state-of-the-art pseudonymisation shall apply.** Moreover, the Emergency Task Force shall adopt measures to ensure adequate data security, including encryption. Finally, regarding data localisation measures, these should be carefully evaluated, for which we suggest to carry out a Data Protection Impact Assessment ('DPIA') in line with Article 39 EUDPR.
- The EDPS notes that Article 18(a) of the Proposal states that, in order to prepare for and support the work of the Emergency Task Force during public health emergencies, EMA "shall develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies". Moreover, Article 18(c) envisages the use of "digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies". However, the Proposal does not provide for a definition of 'electronic health data generated outside the scope of clinical studies', nor any indication about the possible nature or scope of such data. In this context, in order to enhance clarity, **the EDPS recommends include a clear definition of the 'data generated outside the scope of clinical trials'.**
- The EDPS also notes that the section from the 'Context of the proposal', in the Proposal's Explanatory Memorandum, explains that "(...) the proposal will provide useful input to and synergies with the EU Digital Single Market agenda and in the context of the planned European Health Data Space, encouraging and supporting innovation and research, facilitating access to and analysis of data and information, including real world data (health data generated outside the scope of clinical studies) (...)". However, the Proposal does not provide for a clarification on the definition of 'real world data'.
- We understand that, in line with Recital 25 of the Proposal, these 'real time data' could also include data from the EU Space Programme such as the Galileo geolocation services and Copernicus earth observation data. However, for the sake of clarity, **we recommend to clarify the meaning of "real world data", at least by specifying examples of such data and uses.**

⁶ "Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16."

⁷ In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability.

2.3 Transfers of personal data to third countries

- Article 30(5) of the Proposal states that “The Commission, the Agency, and Member States may exchange commercially confidential information and, where necessary to protect public health, personal data, with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.” In this regard, **the EDPS recalls that transfers of personal data to third countries or international organisations must comply with Chapter V of the EUDPR (Articles 46 and following).**

Brussels, 4 March 2021

Wojciech Rafał WIEWIÓROWSKI

(e-signed)