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Dear [...],

Thank you for your consultation of 26 July 2018 concerning the European Reference Networks (ERN) Communication processing operation.

You consulted the EDPS to provide advice on the specific draft privacy statement and draft consent forms that you have developed for this specific processing operation. You also submitted a number of specific questions relating to this processing. Finally, you informed the EDPS that you intend to launch soon a Data Protection Impact Assessment for this processing.

Facts

You submitted a draft notification on the forthcoming processing operation. According to this notification, ERNs for rare diseases are virtual networks bringing together healthcare providers (HCPs) across Europe to improve the diagnosis and treatment of patients with rare, low prevalence and complex diseases. They also serve as research and knowledge centers, updating and contributing to the latest scientific findings in the area of rare and complex diseases. The Networks are set up under Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. The Directive requires the Commission to support Member States in the development of the ERNs.

In order to raise awareness on the existence of the ERNs to allow as many patients as possible to potentially access the ERNs services across Europe, and at the same time to highlight the European added value of the initiative, some communications activities are necessary. These

communication activities are mainly addressed to health care professionals, health NGOs, policy makers, patients and their families, and media.
In order to be effective and relevant, many of these communications activities need to be based on concrete facts and examples of true stories of patients diagnosed and/or treated through the ERNs, giving a human face to the European initiative and providing concrete and tangible outcomes. The communication activities might be of diverse nature: videos, brochures or flyers, website, media articles, infographics, publications.

The processing of personal data will respect the following pathway: for each communication activity which is identified as necessary for the support of the ERN initiative, the Commission will determine what kind of patient profile would be needed. On an ad hoc basis, therefore, the Commission will contact the HCPs members of the ERNs and provide them with the criteria to allow them to identify a few patients matching those criteria. The HCPs will send the Commission the requested cases, with the consent form already filled in by the concerned patients. At this stage the HCP will also provide the Commission with a signed agreement which specifies that health professionals act as a processor on behalf of the Commission, acting only under its instructions and providing the necessary security and confidentiality safeguards, to collect and transfer patients' data for communication purposes.

The Commission will then choose which patient will finally be covered by the communication activity and/or the patient details will be used for it, and will contact him/her requesting a second consent form, giving the patients the possibility to select specific and technically feasible safeguards to be implemented (i.e. blurred faces in videos), in order to protect their identity. In this case, patients might have also to sign an authorisation form for their image rights. The Commission might also process data from the healthcare professionals themselves, as their testimonial and experience within the ERNs would offer a clear added value to communicate on the initiative to their peers. In this case, the same precautions apply for them.

The personal data collected for the selection of the final case(s) will be stored in the Commission's computerized tools and might be used at a later stage for other similar communication activities related to the ERNs. They also might be shared with CHAFEA or INEA for their specific ERN-related communication purposes, as they manage EU financing to the ERN initiative. The patients or healthcare professionals data used for such communication activities will be treated only when relevant for the purpose of communication.

The consent forms signed by the patients/healthcare professionals will specify that the Commission may contact them for the production of one or several of the abovementioned communication tools within a period of maximum three years.

Analysis and recommendations

Given that this processing will take place over the coming years, the EDPS has analysed the file in the light of the upcoming *Regulation on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data* ("Proposal")[1] which will replace the current Regulation (EC) No 45/2001 on the protection of personal data by EU institutions and bodies.

[1] See Position of the European Parliament adopted at first reading on 13 September 2018 with a view to the adoption of Regulation (EU) 2018/… of the European Parliament and of the Council 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, available at http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2018-0348+0+DOC+XML+V0//EN&language=EN#BKMD-6 .

Concerning the different consent forms that the Commission intends to use, the EDPS welcomes the thorough approach of the Commission. The EDPS has only a minor suggestion to add to the consent forms so to draw people's attention to the fact that they may withdraw consent at any time (in line with Article 7 (3) of the Proposal). Therefore the EDPS suggest adding a sentence along the lines of the following example:

"By signing this form, I understand that *I have the right to withdraw my consent at any time. I*f I decide to withdraw my consent for the processing of my personal data in the context of ERN communication activities performed by the European Commission, the European Commission will be able to disable related links on its website concerning the communication product which include my data/testimony (video, article, brochure, and others) and to notify other channels" (italic emphasis added).

Concerning the different questions raised by your consultation, please find the answers below:

1) Transfer of personal data to Executive Agencies

You intend to transfer the data to INEA and CHAFEA, two Executive Agencies linked with DG SANTE for their own communication purposes. You have added a consent box for that in the first step consent (i.e. do you consent that we transfer your personal details to CHAFEA / INEA for them to contact you regarding their own communication purposes).

The EDPS notes that a specific consent from has been added to the form. In this respect, the Privacy statement should explain that the optional data transfer to the Executive Agencies happens takes place only in case of explicit consent (section 7 of the draft Privacy statement).

2) Transfer of personal data to another DG

You also intend to transfer the data to DG COMM for their own communication purposes. You explain that in the notification and in the SPS you have already referred to the European Commission as recipient. You are wondering if that should be subject to consent as well or if it would be ok if you use the consent given to the European Commission.

As long as DG COMM uses the data for the same purpose, e.g. specific communications activities related to the ERNs action, there is no need to require additional specific consent. If DG COMM were to use the data for another purpose, such specific consent would be required.

3) Consent forms

You explain that in your consent forms, you only have a "yes" box. There is no "no" box, by which people could that they do *not* consent to the transfer. You explain that your idea is to be compliant with the data minimisation principle: by not including a "I do not consent" box, you aim to prevent data are collected and transferred to you. That should only happen in case of positive replies. If patients do not consent, no form would be communicated.

The EDPS believes that the different consent forms make it clear to data subjects that the participation in the communication activities is based on explicit consent. It must be made clear to people that they have the choice not to communicate their data and that also if they have given consent, they can withdraw it at any moment.

4) Information of data subjects

Concerning consent form n°2, you are wondering about the correct wording. The text reads as follows:

"I understand that I have the right, as data subject, to access data relating to me, to be informed about the existence and the extent of data processing, to rectify incorrect personal data as the case may be and to oppose further processing on serious and legitimate grounds relating to my particular situation and, in certain cases, to request the erasure of my data."

Article 15 of the proposal lays down the information to be provided to data subjects. According to Article 15 (2) (b), data subjects should be informed about *the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or, where applicable, the right to object to processing or the right to data portability*. The text currently proposed in the consent form and the privacy statement does not match this requirement. To ensure consistency, we therefore recommend using the legal text as provided in Article 15 in the consent form and the Privacy statement.

Concerning the right to object mentioned in the consent forms and in the Privacy statement, please note that this right is not applicable where the processing is based on consent (see Article 23 (1) of the Proposal). The references to the right to object in the consent form and the privacy statement should therefore be deleted.

5) Concerning consent form n°2, you explain that you have left DG COMM's standard wording in the original IRP form:

"[I authorize the EC] to include and archive these photographs and/or films in the European Union's online databases, accessible to the public free of charge online. Third parties having access to these databases may use the said photographs and/or films in compliance with the EC's Decision on re-use of Commission's documents (2011/833/EU) for information or education purposes only."

You would like to check if this is in line with data protection law.

As long as the data subjects consent and the potential withdrawal are respected, the EDPS is not concerned by this formulation.

6) Impact assessment

You explained that you are preparing the Impact Assessment at the same time. In this respect, you would like to know if specific encryption measures have to be put in place when the doctors send you the patients' data. You are wondering whether sending by email is sufficient.

Given that the doctor transmits the consent form including the patient's diagnosis to the Commission, this information constitutes sensitive personal data (see Article 10 of the Proposal). Therefore, particular attention should be paid to the processing of this data, such as its communication. Having said that, the EDPS does not see an obstacle that doctors send the filled consent forms by email. Encrypted email could indeed be a way to protect the sensitive personal data in transit.

My services remain of course available for any question you may have.
Sincerely yours,

Wojciech Rafał WIEWIÓROWSKI

(Signed)

Cc.: [...], DPO European Commission