Deliberation 2020-126 of December 10, 2020Commission Nationale de l'Informatique et des LibertésNature of the deliberation: OpinionLegal status: In force Date of publication on Légifrance: Tuesday January 05, 2021NOR: CNIX2036072VDeliberation n° 2020-126 of December 10, 2020 providing an opinion on a draft decree authorizing the creation of a processing of personal data relating to the management and monitoring of vaccinations against the SARS-CoV-2 coronavirus (request for opinion no. 20020767)The National Commission for Computing and freedoms,

Seizure by the Minister of Solidarity and Health of a request for an opinion concerning a draft decree authorizing the creation of a processing of personal data relating to the management and monitoring of vaccinations against the SARS-CoV-coronavirus 2;

Having regard to Convention No. 108 of the Council of Europe for the protection of individuals with regard to automatic processing of personal data;

Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (GDPR);

Considering the law n° 78-17 of January 6, 1978 modified relating to data processing, files and freedoms, in particular its articles 6-III and 31-II;

Having regard to decree n° 2019-536 of May 29, 2019 as amended, taken for the application of law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms; After having heard Mrs. Valérie PEUGEOT, commissioner , in his report, and Mr. Benjamin TOUZANNE, Government Commissioner, in his observations, Issues the following opinion: The draft decree before the Commission provides for the creation of an information system for the implementation, the monitoring and management of vaccination campaigns against covid-19 called Covid Vaccine (hereinafter, the Covid Vaccine IS), under the joint responsibility of the Directorate General for Health and the National Health Insurance Fund (CNAM) , based on Articles 6.1 e and 9.2 i of the GDPR.

As this decree only sets the legal framework for the Covid Vaccine IS, the Commission will not comment on the conditions for its implementation. On the purposes and interest of the information system The draft decree provides for several purposes aimed mainly at organizing the vaccination of people, the monitoring and supply of vaccines and consumables, the production of information for vaccinated people, the provision of data relating to vaccination for the purposes of calculating indicators and

research, a pharmacovigilance monitoring as well as the financial coverage of acts related to vaccination.

The Commission takes note of the ministry's commitment to clarify the notions of identification and orientation towards an adapted care pathway in the draft decree, the ministry having indicated that these references refer specifically to the orientation of people suffering from adverse effects following vaccination. Subject to this reservation, the purposes appear determined, explained and legitimate, in accordance with Article 5 of the GDPR.

The Commission also notes that this treatment is not intended to be extended to vaccinations other than that against the SARS-CoV-2 coronavirus.

The Commission observes that this processing will be fed, as and when eligibility for vaccination is extended, by successive transfers of data from the databases of the compulsory health insurance schemes and supplemented by health professionals. She observes that in the long term, when the vaccination campaign will be extended to the entire adult population as envisaged by the ministry, the Covid Vaccine IS will include the health data of a major part of the French population. data recipients and usersThe draft decree authorizes many players to be recipients of the personal data contained in the Covid Vaccine IS.

The Commission considers it necessary to recall:- that the data processed within the framework of the Covid Vaccine IS are protected by medical secrecy, as provided for in Article L. 1110-4 of the Public Health Code;

- that under the terms of Article 35 (4°) of Law No. 78-17 of 6 January 1978 as amended, the act authorizing processing pursuant to the provisions of Article 31 must specify the recipients or categories of recipients authorized to receive communication of the data. In this respect, the Commission recalls that only authorized persons and subject to professional secrecy must be able to access data from the Covid Vaccine IS, within the strict limits of their need to know for the exercise of their missions.

It is therefore up to the data controller to define for each recipient functional profiles strictly limited to the needs to know them for the exercise of the missions of the authorized persons. In this respect, it specifies that measures must be put in place as soon as possible so that authorized persons can only access the various data relating to the persons concerned when they actually need it.

The Commission notes, in view of the details provided by the Ministry, that the Covid Vaccine IS will be linked to several information systems already deployed, in particular: the information system relating to the national health identifier (IS INS) ,

the shared medical record (SI DMP) and the adverse event reporting portal (P-SIG). The Ministry also indicated that it plans, during future developments of the Covid Vaccine IS, to connect with third-party patient portals in order to facilitate appointment booking, without however being able, at this stage, to specify which would be the conditions.

Although Article 35 of the Data Protection Act does not require such a level of precision, the Commission considers that the Ministry should mention the list of processing operations and information systems in which the data from the Covid Vaccine IS will be called. to be included, the categories of data transmitted for each of these processing operations or systems, as well as the organizations responsible for this processing. In the event that it does not intend to supplement the decree on this point, the Commission invites the ministry to disseminate this information, for example by making it public on its website.

The draft decree also provides that the digital directorate of the ministries of social affairs (DNUM) will be designated by the general directorate of health (DGS) as a trusted third party in order to direct people towards an appropriate care pathway in the event of 'undesirable effect. To this end, the DNUM will communicate identifying data and will keep them for a period of thirty years for pharmacovigilance purposes. The Commission wonders about the articulation of these missions with those of the National Agency for the Safety of Medicines and Health Products (ANSM), to which the legislator has expressly entrusted the task of ensuring the implementation of the systems of vigilance, relating in particular to vaccines, pursuant to the provisions of Article L. 5311-1 of the Public Health Code.

On this point, the ministry clarified that the DNUM would not be in charge of directing people towards an appropriate care pathway, but only of storing the data under conditions that guarantee its security and integrity. The Commission takes note of this and invites the Ministry to specify the procedures according to which these data may be processed for the purpose of guiding people.

The ministry specified that the DNUM will also be responsible, on behalf of the DGS, for producing steering indicators.

In view of the powers of the DNUM determined by article 6 of decree no. 2013-727 of August 12, 2013, the Commission is surprised at the use of this department for the missions described above.

Finally, it appears that the Ministry and the CNAM plan to use subcontractors for the implementation of the Covid Vaccine IS. In the interests of transparency vis-à-vis the persons concerned, the Commission requests that the principle of recourse to subcontractors be mentioned in the decree and in the event that it does not intend to supplement the decree on this point, the Commission invites the Ministry to disseminate this information, as well as the list of subcontractors, for example by making

them public on its website. It also recalls that the use of subcontractors must comply with the provisions of Article 28 of the GDPR and that agreements must be concluded before any implementation of the processing. It notes that these agreements must in particular provide for the possibility of carrying out audits to ensure the compliance of the processing implemented, and that such audits should be carried out in order to verify the effective application of the obligations provided for in the agreements. The Commission requests that such audits be carried out regularly. On the transmission of pseudonymised data The Commission notes that the list of pseudonymised data transmitted to each organization is not detailed in the draft decree. It recalls that, in accordance with the principle of minimization, provided for in Article 5 of the GDPR, only data that is adequate, relevant and limited to what is necessary with regard to the purposes for which they are processed may be transmitted to the recipients identified in the project. of decree. For transparency purposes, it invites the ministry to specify in the decree the list of data that can be transmitted in this context.

Article 3 of the draft decree provides that the health data platform (PDS) and the CNAM are recipients of pseudonymised data for the purpose of facilitating the use of health data for the purposes of managing the health emergency and the improvement of knowledge about the virus, purposes which do not appear expressly in article 1 of the draft decree. The Commission notes that these purposes are those mentioned in Article 30-I of the decree of July 10, 2020.

The Commission understands that improving knowledge of the virus corresponds to the research purpose mentioned in Article 1 of the draft decree. On the other hand, it wonders about the purpose relating to the management of the health emergency insofar as the project does not seem to be based on the provisions applicable in the context of the state of emergency and where this notion is not mentioned in the purposes described in article 1 of the draft decree. The Commission thus considers that the transmission of data for this purpose cannot be extended beyond the state of health emergency in the absence of provisions providing for their integration into the National Health Data System (SNDS).

The Commission takes note of the Ministry's commitment to indicate the appropriate pseudonymisation measures mentioned in the draft decree should be detailed in the data protection impact analysis which will be sent to it.

The Commission notes, with regard to the details provided by the Ministry, that no data processed within the framework of the Covid Vaccine IS will be transferred outside the European Union and requests that the decree mention this. On the limitation of rights of opposition and deletion of the persons concerned The ministry indicated that the persons concerned could be registered in the SI Vaccine Covid in the following way:

- when the person is selected, according to certain criteria, in the bases of the compulsory health insurance schemes, their data will be transmitted by the organization to the SI Vaccin Covid, with a view to issuing a vaccination voucher;
- when the people are not identifiable or selected in the databases of the compulsory schemes, but meet the vaccination criteria, their registration in the Covid Vaccine IS is carried out by the health professional consulted, only in the event that they wish be vaccinated. The selection criteria that will be used will be established by the High Authority for Health in accordance with Article L. 3111-1 of the Public Health Code, after publication of the decree.

The Commission notes that the draft decree excludes the possibility for data subjects to exercise their right to erasure and their right to object for reasons of public interest.

The Commission welcomes the Ministry's commitment to allow the persons concerned to exercise their right of opposition without limitation until they express their consent to the vaccination procedure. The Commission therefore considers that the right to erasure may also be exercised.

The ministry also clarified that the persons concerned will no longer be able to exercise their right of opposition after expressing their consent to the vaccination act. The Commission considers that this limitation aims to guarantee an important objective of public interest in view of the purposes pursued by the processing, in particular in the context of pharmacovigilance.

Nevertheless, with regard to the right of opposition, article 4 of the draft decree provides that the persons concerned may exercise it for the transmission of data for research purposes to the PDS and the CNAM. The Commission understands that reference is made here to improving knowledge of the virus and that the right of opposition may be exercised without limitation in this case, even after the expression of consent to the vaccination procedure.

It also deduces that the persons concerned will therefore not be able to oppose the transmission of data for the purposes of managing the health emergency mentioned in Article 3-II (4°) of the draft decree.

In view of all of these remarks, the Commission invites the Ministry to fully inform the persons concerned, particularly with regard to the exercise of their rights. It also invites the Ministry to provide a system allowing each person concerned to exercise their right to oppose the transmission of information to the PDS and the CNAM as soon as the file concerning them is created in the Covid Vaccine IS. , for example by the addition of a box to be ticked by health professionals. On the data processed within the framework of the Covid Vaccine IS The Commission invites the Ministry to specify in the decree that the registration number in the national directory of identification of natural persons is treated as a national health identifier.

The Commission also notes that the vaccination locations will be identified and located in the Covid Vaccine IS. As these data may reveal sensitive information concerning the person, such as vaccination in a place of deprivation of liberty, appropriate confidentiality measures must be provided. On security measures The Commission underlines that due to the emergency context the ministry was not able to provide it with the necessary technical information concerning the implementation of the processing. It was therefore not able to verify the compliance of the processing with the GDPR before it was deployed.

The Commission recalls that a data protection impact assessment, which was not provided to it, must be carried out before the processing is implemented. The Commission takes note of the Ministry's commitment to send it to it as soon as possible.

In addition, the Commission specifies that it will be vigilant as to the conditions for implementing the Covid Vaccine IS and that it will exercise its power of control.

M. L. Denis