Deliberation 2021-146 of December 9, 2021Commission Nationale de l'Informatique et des LibertésNature of the deliberation: OpinionLegal status: In force Date of publication on Légifrance: Saturday December 18, 2021NOR: CNIX2137891XDeliberation n° 2021-146 of December 9, 2021 providing an opinion on the decree amending decree no. 2020-551 of May 12, 2020 relating to the information systems mentioned in article 11 of law no. 2020-546 of May 11, 2020 extending the state of health emergency and supplementing its provisions and decree no. 2020-1690 of December 25, 2020 authorizing the creation of personal data processing relating to vaccinations against covid-19 (request for opinion no. 21021673)

The National Commission for Computing and Liberties,

Seizure by the Minister for Solidarity and Health of a request for an opinion concerning the decree amending decree no. 2020-551 of May 12, 2020 relating to the information systems mentioned in article 11 of law no. 2020 -546 of May 11, 2020 extending the state of health emergency and supplementing its provisions and decree no. 2020-1690 of December 25, 2020 authorizing the creation of personal data processing relating to vaccinations against covid-19 ,

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 (General Data Protection Regulation);

Considering the modified law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms; Issues the following opinion: The draft, resulting from an amending referral addressed to the Commission on a draft decree submitted for its examination on December 2, 2021, is mainly intended to modify Article 2 of Decree No. 2020-1690 of 25 December 2020 relating to the Covid Vaccine information system in order to add information, by means of a checkbox, of a vaccination against influenza carried out concomitantly with that against covid-19. In view of the details provided by the Ministry, the Commission specifies that the collection of this information has already been implemented. It nevertheless recalls that such collection should only have taken place after the modification of the regulatory framework applicable to the processing concerned. must be limited and particularly justified so as not to change the very nature of the Covid vaccine treatment. According to the details of the ministry, the recommendation to carry out a double vaccination against influenza and Covid-19 follows an opinion from the High Authority (HAS) dated September 27, 2021, and aims to optimize vaccination coverage against these two epidemics, fight against serious forms of the two diseases and allow better management of epidemics by the health system. As such, the

ministry specified that in addition to the side effects likely to appear, this collection was justified by a risk of a reduction in the immune response to one or other of the vaccines. The decree of June 1, 2021 prescribing the general measures necessary for managing the end of the health crisis was therefore amended on November 5 in order to organize the concomitant vaccination against covid-19 and against seasonal flu. Ministry, the addition of information that a person is concomitantly vaccinated against influenza and covid-19 makes it possible to pursue two purposes: the establishment of pharmacovigilance monitoring and the production of statistics. On the purpose linked to a pharmacovigilance objective As a preliminary point, the Commission notes that the aim pursued by the Ministry, with regard to pharmacovigilance, is not limited to the sole management of the consequences of reports of adverse events, but also tends to scientific evaluation of these possible effects. The modification would also allow health professionals to have this information concerning the patients they treat, in particular in the event that adverse events are reported. According to the details of the Ministry, it is not planned to add to the data contained in the Covid Vaccine information system than a simple checkbox indicating that a vaccine against seasonal influenza was administered at the same time as that against covid-19. The need for this addition stems from opinions no. 2021.0061/AC/SEESP of August 23, 2021 and no. 2021.0069/AC/SESPEV from the Haute Autorité de Santé. concerning the dose of influenza vaccine administered (manufacturer, batch number, etc.) or to have information on the administration of a seasonal influenza vaccine carried out before or after vaccination against Covid-19. Due to the very limited nature of this information, in the event of a pharmacovigilance investigation, the Committee understands that other databases will have to be consulted, in particular those held by pharmacists who have dispensed the product or the medical file of the patient in order to have the necessary information concerning the injections carried out. me d'information Vaccine Covid in order to allow access to it for health professionals responsible for informing the vaccinated person in the event of identification of new risks, is not the recipient of the information relating to the double vaccination.Finally, the Commission recalls that in the current state of the information systems implemented for public health policies, there is, in principle, no centralized file for each vaccination. The Commission stresses that the establishment of a centralized database for vaccination against Covid-19 took place in the context of a health crisis linked to a particularly serious epidemic requiring the organization of a massive vaccination campaign. The addition of data relating to the administration of an influenza vaccine simultaneously with the vaccine against Covid-19 therefore constitutes a significant extension of the data recorded in the Vaccin covid information system, which can only be authorized if its usefulness is sufficiently established. However, given the information communicated to it, the Commission

wonders about the real usefulness of adding this data with regard to the purpose of pharmacovigilance, given the nature very limited in the information it can provide. In addition, it notes that, apart from the opinion of the High Authority for Health, it has not received any details on any studies in progress on the possible interaction between the two vaccines when they are administered simultaneously, or on the first results which would confirm the interest of a systematic and centralized recording. On the purpose linked to the production of statistics In view of the elements previously presented concerning the relevance of the data whose collection is envisaged, the Commission notes that the production of statistics linked to double vaccination could be carried out by means other than the constitution of a centralized and general file containing both health data and identifying data. Under these conditions, if the information concerning a concomitant vaccination was not retained as relevant for the purposes of pharmacovigilance, it should not be collected either for purely statistical purposes. President Marie-Laure DENIS