

DELIBERATION n°2019-112 of SEPTEMBER 5, 2019National Commission for Computing and LibertiesNature of the  
deliberation: AuthorizationLegal status: In force Date of publication on Légifrance: Tuesday, November 05, 2019Deliberation n°  
2019-112 of September 5, 2019 on a single decision and authorizing the company HEVA to implement automated processing  
for research, study and evaluation purposes requiring access to national data from the program for the medicalization of  
information systems (PMSI)(Request no. 919114)The Commission national computing and liberties,Entry by the company  
HEVA of a request for authorization of automated processing for purposes of research, study and evaluation requiring access  
to national data of the program of medicalization of the systems of information; 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 the  
ent (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/CE; Having regard  
to the public health code, in particular its articles L. 6113-7 and L. 6113-8; Having regard to law n° 78-17 of 6 January 1978 as  
amended relating to data processing, files and freedoms, in particular its articles 66, 72 and following; Considering the law n°  
2016-41 of January 26, 2016 of modernization of our health system, in particular its article 193; Considering the decree n°  
2016-1871 of December 26, 2016 relating to the processing of personal data called "National Health Data System"; Having  
regard to decree n ° 2019-536 of May 29, 2019 taken for the application of law n ° 78-17 of January 6, 1978 relating to data  
processing , files and freedoms; Having regard to the decree of March 22, 2017 relating to the security reference system  
applicable to the National System of health data; Having regard to the opinion of the Expert Committee for research, studies  
and assessments in the field of health of March 19, 2019; Having regard to the opinion of the National Institute for Health Data  
of July 8, 2019 on the public interest presented by the processing envisaged by the company HEVA; Having regard to  
deliberation n° 2019-063 of May 09, 2019 referring to the National Institute for Health Data for an opinion on the character of  
public interest presented by the processing envisaged by the company HEVA; Considering the file and its supplements; On the  
proposal of Mrs Sophie LAMBREMON, commissioner, and after having heard the observations of Mrs Nacima BELKACEM,  
commissioner of the Government, Formulates the following observations: Responsible for the treatment Created in 2005, the  
HEVA company analyzes data from the National Health Data System to carry out studies in the field of health. Since 2011, she  
has developed the ADAPT tool (Dynamic Analysis of Attractiveness, Positioning, Hospital Health Territories) designed as a  
decision-making tool. The latter allows health establishments to analyze the care sectors using a set of indicators calculated

from data from the program for the medicalization of information systems (hereinafter "the PMSI") and data available in open -data (data from the annual statistics of health establishments and data from the Hospi-Diag tool managed by the technical agency for information on hospitalization). On the advisability of resorting to the single decision The activities of the data controller, the company HEVA, involve the implementation of data processing from the PMSI in order to feed the ADAPT tool, which in particular allows its various users to formulate requests. The number of annual requests is estimated at several thousand. The processing operations described fall under the processing authorization regime for research, study or evaluation purposes. of this processing on the basis of the provisions of Articles 66 IV, 72 et seq. of Law No. 78-17 of 6 January 1978 as amended (hereinafter the "Informatique et Libertés" law), within the framework of a single decision. On the application of the provisions relating to the SNDSL Since the PMSI data comes from one of the databases making up the National Health Data System (hereinafter "SNDS"), the Commission recalls that all the legislative and regulatory provisions relating to the SNDS is applicable in this case and in particular the ban on using this data for the purposes described in Article L. 1461-1 V of the Public Health Code. On the legality of the processing and the conditions allowing the processing of data concerning health The processing operations implemented by the company HEVA are part of its commercial activity. They are necessary for the purposes of the legitimate interests pursued by the data controller, taking into consideration the very indirectly identifying nature of the data and the guarantees, particularly in terms of personal rights, provided for by the texts governing the provision of SNDS data. article 6, paragraph 1 point f) of the General Data Protection Regulation (hereinafter "GDPR"). In addition, the Commission considers that these processing operations, necessary for scientific research purposes, fulfill the condition provided for in Article 9(2)(j) of the GDPR allowing the processing of data concerning health. On the purpose of the processing operations and their character of public interest The purpose of processing requiring access to PMSI data is to carry out studies intended to construct activity indicators for establishments, groups of establishments or regional hospital groups in order to enable them to: develop medical projects taking into account their environment, in terms of care supply and in terms of costs, and to meet their legal obligation to analyze their activity; to plan the care supply via analysis comparison of care activities, study of recruitment pools (attractiveness, flight), study of collaboration between establishments within a defined perimeter; to enhance the offer of care through the production of indicators for steering and valuing stays. The Commission considers that the purpose of the processing is determined, explicit and legitimate, in accordance with Article 5 paragraph 1 point b) of the GDPR. Furthermore, subject to compliance with the conditions mentioned in the opinion of the

National Institute for Health Data of July 8, 2019, it considers that the processing serves a purpose of public interest, in accordance with Article 66 I of the law "computers and freedoms". On the categories of data processed The Commission recalls that the data controller must only process, for each of the processing operations implemented within the framework of this single decision, the data that is strictly necessary and relevant with regard to the objectives of the processing. Data concerning the following activities are necessary to carry out these studies: medicine, surgery, obstetrics and odontology (MCO). The processing operations included in the framework of the single decision relate to the national PMSI data for the years 2018 to 2020, provided that they are disseminated by ATIH. The Commission recalls that, in accordance with Article 30 of the GDPR, the data controller must keep the list of processing operations carried out under this single decision up-to-date in the register of processing activities. In addition, the adequacy, relevance and limited nature to what is necessary with regard to the purposes for which the data are processed, the geographical area concerned and the historical depth of the data consulted must be justified in this register for each processing implemented in the framework for this single decision. On the data retention period PMSI personal data cannot be stored outside the HEVA secure bubble. Only anonymous results can be exported. The retention period of the data in the secure bubble must be limited to the period necessary for the implementation of the processing, which cannot be more than three years, from the effective access to the data. On the publication of the results The Commission recalls that, when the result of the data processing is made public, the direct or indirect identification of the persons concerned must be impossible, in accordance with article 68 of the law "Informatique et Libertés". The results of queries made within the ADAPT tool will be accessible to healthcare establishments, institutions and healthcare industries that use this tool. access to data under this Single Decision. The data controller keeps up-to-date documents indicating the competent person(s) within it to issue the authorization to access the data, the list of persons authorized to access this data, their respective access profiles and the procedures for allocation, management and control of authorizations. These categories of persons are subject to professional secrecy under the conditions defined by Articles 226-13 and 226-14 of the Criminal Code. The qualification of authorized persons and their access rights must be regularly reassessed, in accordance with the methods described in the authorization procedure established by the data controller. On the information and rights of the persons The information of the persons concerned, as to the possible reuse of their data and the methods of exercise of their rights, is ensured under the conditions provided for in Article R. 1461-9 of the Public Health Code, as well as by a statement appearing on the website of the data controller, health insurance organizations and on media allowing it to be brought to the

attention of individuals, in particular posters in premises open to the public or documents given to them. Access rights , rectification and opposition are exercised with the director of the body managing the compulsory health insurance scheme to which the person is attached, in accordance with the provisions of article R. 1461-9 of the public health code. On data security and traceability of actions The implementation of personal data processing within the framework of the study is carried out under the responsibility of the data controller, including third parties acting on his behalf, in compliance with the provisions of articles 24, 25, 28, 32 to 35 of the GDPR as well as the decree of March 22, 2017 relating to the security reference system applicable to the SNDS. The data will be made available ion with the data controller with a secure bubble. In view of the residual risks and the action plan identified and accepted by the HEVA company in its approval decision dated April 9, 2019, the processing seems to comply with the requirements laid down by Articles 5 paragraph 1) point f) and 32 of the General Data Protection Regulation, as well as the security baseline applicable to the SNDS appended to the order of 22 March 2017. The Commission recalls that only data from anonymization process, in such a way that the direct or indirect identification of persons is impossible, may be extracted. To take advantage of the anonymity of a data set, the data controller must carry out an analysis to demonstrate that its anonymization processes comply with the three criteria defined by Opinion No. 05/2014 on anonymization techniques adopted by the Article 29 group (G29) on April 10, 2014. Failing that , if these three criteria cannot be met, a study of the risks of re-identification must be carried out. ten. However, it draws the data controller's attention to the fact that the deletion of results containing small numbers may not be sufficient to meet the three criteria defined by the above-mentioned opinion no. 05/2014 and that a complete analysis of its anonymization processes must be carried out, accompanied by a regular reassessment of the risks of re-identification. On the principle of transparency The provision of data from the SNDS and its components is designed in such a way as to account for their use at Civil society. To this end, Article L. 1461-3 of the CSP makes access to data from the SNDS and its components subject to the communication to the National Institute of Health Data (INDS) of several elements by the data controller, before and after the studies. Thus, the data controller undertakes to register with the public directory kept by the INDS all the studies carried out within the framework of this single decision. This registration, to be carried out by the data controller or the person acting on his behalf, before the start of the processing, is accompanied by the transmission to the INDS of a file comprising: the protocol, including the justification of the interest public, as well as a summary, according to the model made available by the INDS; the declaration of interests of the controller, in relation to the purpose of the processing. At the end of the studies, the method and the results obtained must

be communicated to the INDS for publication. The recording of the processing and the transmission of the results are carried out in accordance with the methods defined by the INDS. In addition, the Commission takes note of the commitment of the HEVA to implement efforts of additional transparency vis-à-vis civil society through the annual publication on its website of the list of processing carried out within the framework of the single decision as well as the number of requests made using the ADAPT tool. The Commission also recalls that at the end of the three-year period, a report containing in particular the list of analyzes carried out within the framework of the single decision as well as the methodology followed within the framework of the analyzes must be sent to the Commission. On external audits The data controller must carry out an independent external audit at the end of the three-year period in order to ensure compliance with the principles laid down by law, in particular compliance with prohibited purposes. This audit must cover the purposes pursued and the use by the data controller of the results of the studies carried out. An audit report must be sent to the chairman of the SNDS audit committee provided for by the "Informatique et Libertés" law. Authorizes, in accordance with this deliberation, the company HEVA to implement the processing described above for a period of three years, with the obligation, on the one hand, to submit a report to the Commission at the end of this deadline and, on the other hand, to carry out an independent external audit. For the

President Deputy Vice-President Sophie LAMBREMON