

DELIBERATION n°2019-090 of JULY 18, 2019 National Commission for Computing and Liberties Nature of the deliberation:

Authorization Legal status: In force authorizing HosMedis 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. 919025)The Commission National Computing and Liberties, Entry by the company HosMedis of an

application for authorization of automated processing for research, study and evaluation purposes requiring access to national data from the program for the medicalization of medical systems '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

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/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 ° 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 decree n ° 2016-1871 of December 26, 2016 relating to the processing of personal data called

"System National Health Data"; Having regard to the decree of March 22, 2017 relating to the security reference system

applicable to the National System health data; Having regard to the opinions of the Expert Committee for research, studies and

assessments in the field of health of November 20, 2018 and December 18, 2018; Having regard to the file and its

supplements; On the proposal of Mrs. Valérie PEUGEOT, commissioner, and after having heard the observations of Mrs.

Nacima BELKACEM, government commissioner, Makes the following observations: Responsible for processing Created in

2011, HosMedis is a consulting and research company specializing in the construction of indicators of hospital activity for the

purpose of promoting the supply of care. To do this, it has developed management solutions for analyzing real-life health data

such as data from the information systems medicalization program (hereinafter "PMSI"). These solutions include the HospiLink

GHT and HospiLink ARS tools intended respectively for regional hospital groups and regional health agencies. On the

appropriateness of recourse to the single decision The activities of the data controller, and more particularly the development

of the aforementioned applications, involve the implementation of around one hundred data processing operations from the

information systems medicalization program (PMSI). The processing operations described come under the processing

authorization system for research, study or evaluation purposes. The Commission considered it appropriate, in view of the elements presented in the application file, to authorize the implementation of this processing on the basis of the provisions of the articles 66 IV, 72 et seq. of law n° 78-17 of January 6, 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 PMSI data being taken 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 are applicable in this case and in particular the prohibition 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 implemented by the company HosMedis is part of its commercial activity. They are necessary for the purposes of the legitimate interests pursued by the data controller, with regard to 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. This processing is, in this respect, lawful with regard to Article 6, paragraph 1 point f) of the General Data Protection Regulation (hereinafter "GDPR"). Furthermore, the Commission considers that these processing operations, necessary for scientific research purposes, fulfill the condition laid down in Article 9 paragraph 2 point j) of the GDPR allowing the processing of data concerning health. On the purpose of the processing and its nature in the public interest Processing requiring a n access to PMSI data is intended to carry out studies intended to analyze and evaluate the supply of care in a territory or region in order to adapt it and measure the effects of the measures of the arrangements made thanks to: monitoring of the medical project and the quality of care for the purpose of improving inter-establishment and inter-field sectors within a territory; the characterization of patients; the evaluation of patient flows and their care pathways; the evaluation of the adequacy of the care offer to the health needs of a territory or a region; the evaluation of the impact of the regional health plans put in place on a region or a territory 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, it considers that the processing serves a purpose of public interest, in accordance with the Article 66 I of the "Informatique et Libertés" law. 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 strictly necessary and relevant with regard to the objectives of the treatments. In addition to the specific file allowing all the PMSI data concerning the same patient to be linked (file "ANO"), the data concerning the following activity are necessary for the real

ization of these studies: medicine, surgery, obstetrics and odontology (MCO); follow-up care and rehabilitation (SSR); home hospitalization (HAD); additional file (FICHCOMP). The processing operations included in the framework of the single decision relate to the national PMSI data for the years 2013 to 2020, provided that they can be disseminated by ATIH. The Commission recalls that, in accordance with the Article 30 of the GDPR, the data controller must keep up to date, within the register of processing activities, the list of processing operations implemented within the framework of this single decision. 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 platform of the Secure Data Access Center (hereinafter "CASD") ) by the data controller, their export being prohibited. Only anonymous results can be exported. The duration of access to the data in the secure platform must be limited to the duration necessary for the implementation of the processing, which cannot be more than three years, from the date of access. 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 the studies carried out within the framework of this single decision may in particular be sent to the directors of establishments as well as to the directors of the regional health agencies. On the categories of data recipients Only the data controller and the persons authorized by him have access to the data within the framework of 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 or with the data controller via the secure access provider designated by ATIH, namely the CASD. Only data resulting from anonymization processes, such that the direct or indirect identification of persons is impossible, may be subject to extraction. by opinion no. 05/2014 on anonymization techniques adopted by the Article 29 group (G29) on April 10, 2014. Failing this, if these three criteria cannot be met, a study of the risks of re-identification must be carried out. The Commission notes that, subject to a regular reassessment of the risks, no results are accessible in the HospiLink GHT and HospiLink ARS applications when the number of people concerned is strictly less than ten. However, the Commission 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 anonymisation processes must be carried out. 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 to 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 company HosMedis to implement additional transparency efforts vis-à-vis of 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 aggregated results of the evaluations carried out using PMSI data. On external

audits The data controller must carry out an independent external audit internally 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 HosMedis to implement the processing operations 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 period and, on the other hand, to carry out an independent external audit. The President Marie-Laure DENIS