

DELIBERATION n°2019-004 of JANUARY 10, 2019 National Commission for Computing and Liberties Nature of the
deliberation: Authorization Legal status: In force Date of publication on Légifrance: Wednesday March 27, 2019 Deliberation n°
2019-004 of January 10, 2019 on a single decision and authorizing Altense Engineering to implement automated processing
for research, study and evaluation purposes requiring access to national data from the information systems medicalization
program (PMSI) (Authorization request no. 918291) The National Commission for Computing and Liberties, Entry by the
company Altense Engineering of a request for authorization of automated processing for research, study and evaluation
purposes requiring access to national program data of medicalization of information systems; Having regard to Convention No.
108 of the Council of Europe for the protection of individuals with regard to automatic processing of data 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 natural
persons with regard to the processing of personal data and on the free movement of such data , and repealing Directive
95/46/EC; Having regard to Law No. 78-17 of 6 January 1978 as amended relating to data processing, files and freedoms, in
particular its Articles 8-II-8°, 54, 61 and following; Considering the law n° 2016-41 of January 26, 2016 of modernization of our
health system, in particular its article 193; Having regard to Decree No. 2005-1309 of October 20, 2005 as amended, taken for
the application of Law No. 78-17 of January 6, 1978 relating to data processing, files and freedoms; Having regard to Decree
No. 2016-1871 of December 26, 2016 relating to the processing of personal data called "National Health Data System"; Having
regard to the decree of March 22, 2017 relating to the security reference system applicable to the National Health Data
System; Having regard to the opinions of the Expert Committee for research, studies and assessments in the field of health of
June 27, 2018 and July 18, 2018; Having regard to the file and its supplements; On the proposal of Mrs Marie-France
MAZARS, commissioner, and after having heard the observations of Ms. Nacima BELKACEM, Government commissioner,
Makes the following observations: Responsible for processing Specialized in market studies and surveys, the company Altense
Engineering offers hospital activity analysis services to intended for health establishments and regional health agencies. On
the advisability of using the single decision The activities of the data controller involve the implementation of several data
processing operations of the program for the medicalization of information systems (PMSI) intended for the development of
hospital activity indicators. The treatments described fall under the authorization of treatment for research purposes e, study or
evaluation. 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 Articles 54 IV and 61 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. Health (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; compliance with the safety standards applicable to the SNDS, set by the decree of March 22, 2017.

On the lawfulness of processing The processing operations implemented by Altense Engineering are part of as part of its corporate purpose 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, in particular in terms of the rights of individuals, provided for by the texts governing the provision of the data. This processing is, as such, lawful under Article 6, paragraph 1 point f) of the General Data Protection Regulation (hereinafter "GDPR"). On the purpose of the processing and its nature of interest public The purpose of the processing operations requiring access to PMSI data is to carry out epidemiological and medico-technical studies allowing the construction of a tool for analysis, planning and evaluation of the care offer. The Commission considers that the purpose of the processing is determined, explicit and legitimate, in accordance with Article 5(1)(b) of the GDPR. Furthermore, it considers that the processing serves a purpose of public interest, in accordance with Article 54 I of the law "computing 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 strictly necessary and relevant with regard to the objectives of the processing. Provided that these files can be distributed by ATIH, in addition to the specific file used to link all the PMSI data concerning the same patient ("ANO" file), the data concerning the following activities are necessary to carry out these studies: medicine, surgery, obstetrics and odontology (MCO); follow-up care and rehabilitation (SSR); collection of medical information in psychiatry (RIM-P); hospitalization at home (HAD); The processing operations included in the framework of the single decision relate to the national PMSI data for the years 2017 to 2018 as well as to the monthly data, provided that they can be disseminated by ATIH. 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 for each ue processing implemented within the framework of this single decision in the register of processing activities provided for in Article 30 of the GDPR. On the retention period of data PMSI personal data cannot be subject to storage 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 data in the secure platform must be limited to the duration necessary for the implementation of processing, which may not exceed one year. On the publication of results The Commission reminds 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 56 of the law "Informatique et Libertés". The results of the studies carried out within the framework of this single decision may be addressed to public and private health establishments as well as to regional health agencies. On the categories of data recipients Only the data controller and the persons authorized by him have access to the data in the context 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 ion with the data controller via the secure access provider designated by ATIH, namely 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 -identification 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 INDS of several elements by the data controller, before and after the studies. Thus, the data controller undertakes to register the studies carried out within the framework of this single decision with the public directory kept by the INDS. 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. The data controller having benefited from two reserved opinions and a deemed favorable opinion from the Expert Committee for Research, Studies and evaluations in the field of health, the authorization will be limited to a period of one year, with an obligation to submit a report to the Commission at the end of this period. The latter must contain the list of analyzes carried out within the framework of this single decision as well as the methodology followed in the context of the analyses. Authorizes, in accordance with this deliberation, the company Altense Engineering to implement the processing operations described above for a period of one year, with the obligation to submit a report to the Commission at the end of this period.

For the President The Deputy Vice-President Marie-France MAZARS