

Deliberation 2018-334 of October 18, 2018 National Commission for Computing and Liberties Nature of the deliberation: Single decision Legal status: In force Date of publication on Légifrance: Thursday, December 20, 2018 "APM International" 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. 918256 ) The National Commission for Computing and Liberties, Seizure by the company APM International of a request for authorization of automated processing for research, study and evaluation purposes requiring access to national data from the program 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 personal data personal character; 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; Having regard to Law No. 78-17 of 6 January 1978 as amended relating to data processing, files and freedoms, in particular 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; Considering the decree n° 2005-1309 of the modified October 20, 2005 taken for the application of the law n° 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 the National Health Data System Having regard to the decree of 22 March 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 25, 2018 and July 18, 2018; Considering the file and its supplements; On the proposal of Mrs Marie-France MAZARS, commissioner, and after having heard the observations of Mrs. Nacima BELKACEM, Government Commissioner, Makes the following observations: Responsible for processing APM International is a press agency specializing in the health sector founded in 1989. As part of its information activity health professionals, it deals with subjects related to health policy, public and private establishments, scientific news and the life of health industries. To do this, it analyzes health policies at regional and national level as well as the hospital landscape using activity indicators by establishment. This analysis, previously carried out in collaboration with design offices, is now intended to be internalized. On the advisability of using the single decision The editorial project of the data controller involves the rapid implementation of many data processing operations in the program of medicalization of information systems (hereafter PMSI) intended for the analysis of health policies. The processing described falls under the processing authorization regime 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 Articles 54-IV and 61 et seq. of Law No. 78-17 of the January 6, 1978 amended (hereinafter the Data Protection Act), within the framework of a single decision. On the application of the provisions relating to the SNDS The PMSI data being taken from one of the databases making up the National Data System of 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 reference framework applicable to the SNDS, set by the decree of March 22, 2017; The principle of transparency provided for in article L.1461-3 of the public health code : transmission of the protocol, the declaration of interests and t of the results to the National Institute for Health Data (hereafter INDS).On the legality of the processingThe processing carried out by the data controller falls within the framework of its editorial policy: information health sector by means of a factual and in-depth analysis of hospital issues. Processing is necessary for the purposes of the legitimate interests pursued by the controller and 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 in the public interest The processing operations requiring access to PMSI data are intended to carry out studies relating to the analysis of public health policies, their results as well as the health landscape with the construction of activity indicators by establishment or by hospital group in the territory. The Commission considers era that the purpose of the processing is determined, explicit and legitimate, in accordance with Article 5 paragraph 1 point b) of the GDPR. In addition, it considers that the processing serves a purpose of public interest, in accordance with Article 54 I of the Data Protection Act. 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 making it possible to link all the PMSI data concerning the same patient (ANO file), the data concerning the following activities are necessary for the performance of these studies: medicine, surgery, obstetrics and odontology (MCO); home hospitalization (HAD). additional file (FICHCOMP). Treatments included within the framework of the single decision relate to the national data of the PMSI whose maximum historical depth is nine years plus the current year.The adequacy, relevance and limited 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 processing implemented within the framework of this single decision in the register of processing activities provided for in Article 30 of the GDPR. Data retention PMSI personal data may not be retained 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 the processing. When the data controller justifies it, access to the data may be maintained at the end of the study, within the limit of two years from the last publication relating to the results. 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 56 of the Data Protection Act.

On the categories of data recipients Only the 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 ion with the data controller through the secure access provider designated by ATIH, CASD. object of an extraction.

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 procedures defined by the INDS. In accordance with the recommendations of the Expert Committee for research, studies and evaluations in the field of health, the authorization will be limited for 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, the publication media as well as the methodology followed in the context of the analyses. Authorizes, in accordance with this deliberation, the company APM International to implement the aforementioned processing for a period of one year, with an obligation to submit a report to the Commission at the end of this period. For the President

Deputy Vice-President Marie-France MAZARS