Deliberation 2018-289 of September 12, 2018 National Commission for Computing and Liberties Nature of the deliberation: Authorization Legal status: In force Date of publication on Légifrance: Friday, October 05, 2018 Deliberation n° 2018-289 of July 12, 2018 authorizing the company IQVIA Opérations France to implement automated processing of personal data for the purpose of setting up a warehouse of personal data for the purposes of research, study or evaluation in the field of health, referred to as a database LRX (n° 2120812) The National Commission for Computing and Liberties, Seizure by the company IQVIA Opérations France of a request for authorization concerning the automated processing of personal data for the purpose of setting up a warehouse of personal data, including in particular health data, for the purposes of research, study or evaluation in the field of health, referred to as the LRX database; 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 April 27, 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 Articles L. 1461-1 et seq. of the Public Health Code; 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°, 22 and 53 and following; Considering the decree n° 2005-1309 of October 20, 2005 modified taken for the application of the law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms; After having heard Mrs Valérie PEUGEOT, Commissioner , in her report, and Ms. Nacima BELKACEM, Government Commissioner, in her observations, Formulates the observations ervations: The National Commission for Computing and Liberties has been seized by the company IQVIA Opérations France (hereinafter IQVIA) of a request for authorization relating to the constitution of a data warehouse including in particular data from health of a personal nature, for the purpose of research, study or evaluation in the field of health, referred to as the LRX database, in support of which a data protection impact analysis has been produced. IQVIA, a simplified joint-stock company with a single shareholder, is the result of the merger of the companies IMS Health, whose historical core business is the supply of regularly updated data on the volumes of drugs sold in pharmacies, and Quintiles, a specialist in studies and advice for the drug industries and health players. In order to implement this treatment, IQVIA has submitted an application for authorization to the Commission based on articles 8-IV and 25-I-1° of Law No. 78-17 of January 6, 1978 as amended (hereinafter the Data Protection Act or Law) relating to the processing of so-called sensitive personal data justified by the public interest then in force at the time of the referral. On the legal basis of the processing, its purposes and its nature of public interest The legal basis of the processing

retained is that of the legitimate interests pursued by the controller pursuant to Article 6-1- f of the General Data Protection Regulation (GDPR). The constitution of the personal health data warehouse is intended to enable non-interventional studies aimed at evaluating the proper use of the drug in real life, the scientific and statistical analysis of phenomena related to the persistence , compliance, compliance with requirements and contraindications. The Commission considers that the purpose of the processing presented is determined, explicit and legitimate, in accordance with the provisions of Article 5-1-b of the GDPR. Regarding the requirement, required by law, the existence of a public interest in order to process personal health data outside of healthcare activities or the consent of the persons concerned, the Commission notes that the pursuit of the public interest does not is not reserved for public persons only. read on D+1, to inform both private and public players about the proper use of medicines, the identification of drug interactions, patient care, treatment compliance. Thus, the Commission considers that the constitution of this warehouse of data from community pharmacies for the purposes of research, study or evaluation in the field of health, is of public interest. The Commission recalls that future uses of the data contained in this warehouse will fall within the framework of the provisions of section 2 of chapter IX of the law which also require that each request for research, study or evaluation meet a requirement of public interest. Thus, the Commission considers that the use of data contained in the processing that will be implemented by IQVIA cannot, by analogy with the prohibited purposes of use of the National Health Data System (SNDS), be used for the purposes of: promoting products health cases aimed at health professionals or health establishments; or for the purpose of excluding guarantees from insurance contracts and modifying contributions or insurance premiums for an individual or a group of individuals presenting the same risk. In order to guarantee the character of public interest of the future uses of the data, the Commission notes that IQVIA plans to set up a governance based on two ad hoc committees, an operational committee for the governance of data and a strategic committee, both responsible for examining the research or study projects of the company's future clients with regard to the public interest according to a validation procedure based on a pre-established analysis grid. The analysis includes information relating to the purpose of the study, the context of the request, the author of the request, the granularity of the information requested and the final recipients and makes it possible to check whether the research project research or study is in the public interest. It is completed by authorized IQVIA personnel responsible for implementing an analysis and may be audited at any time by the Strategy Committee. In case of doubt on the existence of a public interest, the Operational Committee is seized to rule on the question of the public interest. He can in turn refer the matter to the Strategy Committee, which decides as a last resort. LRX. The Commission acknowledges

that IQVIA undertakes to publish annually a global summary of the types of analyzes carried out using data from the LRX database, some of which may be published subject to the agreement of their customer. The Commission welcomes IQVIA's proposal to send it an annual report summarizing the operation of the LRX database and the requests made.On the nature of the data processedThe following data will be collected:concerning the pharmacy customer: the NIR, year of birth, first name and sex, so-called issue data, consisting of health data relating to the dispensing of health products concerning him with the content of these dispensations; concerning prescribers: the data of identification of the prescriber (RPPS or Adeli code), the specialty and the geographical area of the prescriber, the establishment code; concerning the partner pharmacist: the code and the geographical area of the partner pharmacy. The Commission considers that the data processed is adequate, relevant and not excessive with regard to the purpose pursued, in accordance with the provisions of Article 5-1-c of the GDPR. System envisaged and the data pseudonymization process The first stage of data processing is carried out within the pharmacy itself. It consists of calculating the INS-C from the patient identification data and their NIR. Once the INS-C has been calculated, it is hashed using the SHA-256 algorithm. The identifiers thus obtained associated with the health product dispensing data are then transmitted encrypted by e-mail to a trusted third party. This performs a new data hashing operation using a secret key. The data thus obtained is then transmitted to a second trusted third party that also hosts health data. This will encrypt the identifiers generated by the first trusted third party using the AES algorithm and a 256-bit key, then replace the identifiers thus obtained with random identifiers stored in a correspondence table. The random identifiers are then transmitted to IQVIA along with the health product dispensation data. In the event of compromise, or every three years, the encryption key will be renewed. In the current state of the art, and in view of the security measures put in place elsewhere, the Commission considers that the planned pseudonymization process will in the sense of the recommendations pushed by the GDPR by reducing the possibilities of re-identification of the persons whose data are processed to what is strictly necessary in this context. risks for the persons concerned, and in no way exonerates the data controller from his obligations. On the data retention period The data controller wishes to keep the data of patients, prescribers and pharmacists for a period of ten years in order to be able to carry out analyzes over long periods of time, the usefulness of which has been proven in terms of drug consumption. The Commission considers that this The data retention period does not exceed the period necessary for the purpose for which they are collected and processed, in accordance with the provisions of Article 5-1-e of the GDPR. On the recipients of the data Have access to the database data LRX data authorized IQVIA personnel and IQVIA subcontracting companies. Scientific

partners such as INSERM will also be able to access the LRX database to carry out study projects subject to CNIL formalities. This access will be reserved for persons designated by name from a dedicated workstation located on IQVIA's premises and subject to compliance with a confidentiality agreement. The customers targeted by IQVIA are mainly manufacturers in the health sector or the public authorities (for example, the High Authority for Health, the Ile-de-France Regional Agency, etc.). The Commission notes that IQVIA customers will not be recipients of individual data relating to pharmacy customers. The Commission considers that the categories of recipients and the methods of communicating the results do not call for comment. attention of the data controller to the obligations incumbent upon him in terms of data confidentiality and reminds that he must: respect and ensure respect for the secrecy of information by all persons likely to work on this data; not to retrocede or disclose to third parties the individual information provided in any form whatsoever; not to carry out comparisons, interconnections, connections, pairings with any directly or indirectly nominative data file or any information likely to reveal the identity of a person and/or or his state of health; not to misuse the information collected, nota for purposes of research or identification of individuals. On information and the rights of individuals Community pharmacists will be contractually responsible for individually informing their customers of the processing of data concerning them, as well as for allowing the exercise of the rights of access, rectification and opposition which are recognized to them. It is expected that people will be informed individually by the delivery of an information notice. This information will be supplemented by a document displayed in the community pharmacy or distributed on its website. 2016/679 of the European Parliament and of the Council of 27 April 2016. The Commission notes that the right of opposition is exercised with partner community pharmacies. The pharmacist equipped with a barcode indicates in his tool that the person has exercised his right of opposition so that his data does not feed the data warehouse. All data is deleted, including data already collected in the event of the exercise of the right of opposition during processing. Partner pharmacists will be informed individually by IQVIA via their personal space in the tool and an email that their IQVIA address. The Commission requests that these statements be completed in order to cover all the information provided for in Articles 12 and 13 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016. The rights of pharmacists s will work with IQVIA's legal department. The Commission notes that IQVIA specifies that it is not able to individually inform prescribers whose RPPS code, or failing that, the Adeli code, is collected, insofar as it does not have the contact details of the latter, except to collect additional data (such as the e-mail and/or postal address of the prescriber) which the company does not need for the constitution of the a LRX database and subsequent treatments. Prescribers will be

informed by postings distributed within partner pharmacies which will refer them to the IQVIA website for more complete information. The Commission requests that the information comply in all respects with provisions 12 and 14 of the GDPR, regardless of the medium envisaged. It also requests that the information be disseminated more widely, by means of other media, in order to guarantee the respect of the right to information of the persons concerned.Prescribers will exercise their rights with IQVIA.On data security and the traceability of actionsThe Commission notes that the company IQVIA relies, among other things, on an architecture which has obtained HDS approval. Data exchanges will be carried out via encrypted communication channels and ensuring the authentication of the source and the destination: data transmitted by pharmacies are transmitted by encrypted emails, and data transmitted by trusted third parties are encrypted via the SFTP protocol. Authorization profiles are provided in order to manage access to data as needed. The Commission notes that authorizations are reviewed every 6 months and that a process for deactivating user accounts has been put in place in order to manage changes in assignment and the departure of authorized persons.Concerning the authentication of users, the Commission notes that the data controller has implemented an authentication policy defining the procedures for authenticating the different types of authorized persons. The Commission notes that the rules put in place comply with deliberation no. 2017-012 of January 19, 2017 adopting a recommendation on passwords. Logging of connections to the application as well as consultation operations, creation, modification and deletion carried out in the treatment will be carried out. Regular trace analysis should be performed. The Commission recommends, in this respect, that this control of traces be carried out automatically, in order to detect abnormal behavior and raise alerts. The Commission notes that the data controller has undertaken to keep the logs for a period of six months. The maintenance interventions will be subject to traceability and are carried out in the presence of a computer specialist from the company. Procedures have been put in place to ensure the confidentiality of the data contained on the storage media sent for maintenance. Measures are planned to ensure the security of the network, in particular by implementing its compartmentalization. the impact analysis relating to data protection carried out by the company, the Commission requests that it be supplemented, before the implementation of the processing, by an analysis of the sources of risks, the essential assets and the supporting assets and that specific and detailed risk scenarios are identified and estimated in terms of likelihood and severity. Subject to the above observations, the security measures described by the data controller comply with the state of the art. However, the Commission recalls that the data controller must continuously ensure that the security measures put in place make it possible to guarantee that the risks to individuals remain at an acceptable level. The

Commission recalls that this obligation requires updating security measures with regard to the regular reassessment of the risks. Under these conditions, the Commission authorizes the company IQVIA Opérations France to implement the processing of personal data for the purpose of creating a warehouse of personal data for the purposes of research, study or evaluation in the field of health, derived from data from community pharmacies.Finally, it recalls that the processing of personal health data which will be implemented subsequently to for purposes of research, study or evaluation in the field of health are distinct processing operations which must be subject, by the company IQVI A, specific formalities provided for in chapter IX section 2 of the law. The President I. FALQUE-PIERROTIN