CNIL Adopts Blanket Authorization for Pharma Industry

The French data protection authority (hereafter: "CNIL") recently made public an important decision for the pharmaceutical industry. In a Decision No 2014-501 of December 11, 2014, the CNIL issued a Blanket Authorization in which it simplified the registration requirements for the processing of certain patient data by laboratories.

The Blanket Authorization covers pharmaceuticals that may be prescribed by doctors for the treatment of certain pathologies and that are subject to:

(i) A temporary authorization of use (hereafter: "TAU") for pharmaceuticals which are in the final evaluation phase prior to being commercialized ; or

(ii) A temporary recommendation of use (hereafter: "TUR") for pharmaceuticals which are available on the market but are in the process of being updated.

In a TAU and a TUR, the National Agency for Medicine and Pharmaceutical Safety (hereafter: "NAMPS") defines protocols for the monitoring of patients. In the course of a medical treatment, patient data are exchanged between the laboratories, the prescribing doctors, and the NAMPS for monitoring and compliance purposes. In this process, laboratories must assess whether the risks associated with a specific treatment are within acceptable safety parameters.

Laboratories may process patient data under the Blanket Authorization (without further specific CNIL authorization) under the following conditions:

(i) Purposes of the Processing: Laboratories process patient data for the purposes of the prescription, monitoring and possible termination of a medical treatment. Furthermore, they collect the contact details of the prescribing doctors and pharmacists for administration purposes.

(ii) Categories of Data Processed: Laboratories process (i) patient data (alphanumeric code, identifying data such as gender, weight, age and date of birth), (ii) health data (health protocol, medical history, family background, on-going treatments, tests and results, secondary effects), and (iii) identifying data of the prescribing doctors and pharmacists. Data on the patient's ethnic origin, sexual life, and consumption of tobacco, alcohol and drugs may be collected only if they are strictly necessary for the treatment of the specific pathology at hand.

(iii) Data Retention Period: The data may not be retained more than 10 years after the pharmaceuticals are commercialized. After this period, the data should be suppressed or anonymized and archived.

(iv) Authorized Personnel: Only some specific employees are entitled to access the patient data. In a laboratory, the members of the following departments qualify as authorized personnel: the treatment supervision team, the drug monitoring department, the research and development department, the distribution department, and the audit department.

Furthermore, service providers, partners, the NAMPS, and the public authorities – national, regional or European – responsible for drug monitoring may have access to the data. Companies of the same pharmaceutical group may also have access to the data.

(v) Notice to the Patients: The prescribing doctor must deliver a notice to the patients containing a specific reference to the patient's right to access and modify his/her personal data. The notice should also specify whether international data transfers occur.

(vi) Information Security: Laboratories must implement a specific security policy that sets forth security measures pertaining to (i) the protection of the laboratory premises, (ii) the authorizations for data access, including the authentication procedures, the tracking of access to medical information and log history, and (iii) data transfers. Moreover, where doctors and pharmacists exchange patient related data on a platform, the access should be secured through an authentication procedure and use of a professional health card or a similar tool. Emails must be encrypted and accessed through a private key. Contracts with service providers must contain a confidentiality clause and set forth provisions for the remit of the data at the end of the provision of the service.

(vii) Registration with the CNIL: Laboratories may register their processing through a declaration of conformity by which they declare that they comply with the requirements set out in the Blanket Authorization. All processing that would exceed the requirements of the Blanket Authorization require a prior authorization from the CNIL.

In a press release, the CNIL stated that it wanted to promote innovation in the pharmaceutical industry while meeting patients' expectation of privacy.

The CNIL Decision No 2014-205 is available (in French) at:
http://www.cnil.fr/documentation/deliberations/deliberation/delib/327/

The CNIL Press Release is available (in French) at: http://www.cnil.fr/les-themes/sante/actualite/article/laboratoires-adoption-dune-autorisation-unique-pour-les-atu-et-les-rtu-au-041/

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