CNS 14/2020

Opinion in relation to a hospital's consultation on access to data of its professionals in the framework of a scientific study carried out in another hospital

A letter from the data protection officer (hereafter, DPD) of a hospital (hereafter, Hospital A) is presented to the Catalan Data Protection Authority in which he asks whether access to the data of the center's professionals that have had positive results in the Covid19 detection tests, which would be recorded in the Department of Health's Covid19 register, by the research team of another hospital (hereinafter, Hospital B), with the purpose of applying their recruitment in a scientific study that is being carried out, is legitimate. It is also
raises whether Hospital A could have access to the data of this register for the same purposes of scientific research.

Having analyzed the request and seen the report of the Legal Counsel, the following is ruled.

I

(...)

II

The DPD states in its inquiry that the research team of Hospital B has contacted some of the medical professionals of Hospital A who have had positive results in the tests for the detection of Covid19, with the intention of recruit them for the scientific study that is being developed from Hospital B.

He points out that, according to the protocol of the clinical trial in question provided to them by the Research Ethics Committee of Hospital B, the source of this data is the Covid19 register of the Department of Health, specifically, the Epidemiological Surveillance Emergency Service of Catalonia (SUVEC), recipient of notifications of positive cases of Covid19 that are carried out in compliance with Decree 203/2015, of September 15, which creates the Epidemiological Surveillance Network and notification systems for notifiable diseases and epidemic outbreaks are regulated.

Given this, it raises the following questions:

- If the access to the health data of the medical professionals of Hospital A referring to the positive results due to infection by Covid19 by the research team of Hospital B through the assignment of the same directly from the Covid19 register of the Department of Health is legit.

- If Hospital A could also have access to health data of medical professionals from other hospital centers for purely clinical research purposes, in the event that it is considered appropriate and provided that all necessary approvals have been obtained.

III

The Regulation (EU) 2016/679, of the Parliament and of the European Council, of April 27, 2016, General Data Protection (hereafter, RGPD)), establishes that all processing of personal data must be lawful, loyal and transparent (article 5.1.a)).

Article 6.1 of the RGPD regulates the legal bases on which the processing of personal data can be based. Specifically, section e) provides that the treatment will be lawful if "it is necessary for the fulfillment of a mission carried out in the public interest or in the exercise of public powers conferred on the person responsible for the treatment".

Article 6.3 of the RGPD establishes that the basis of the treatment indicated in this article 6.1.e) must be established by the Law of the European Union or by the law of the Member States that applies to the person responsible for the treatment.

The reference to the legitimate basis established in accordance with the internal law of the Member States referred to in this article requires that the rule of development, when dealing with the protection of personal data of a fundamental right, has the status of law (Article 53 CE), as recognized in Article 8 of Organic Law 3/2018, of December 5, on the protection of personal data and the guarantee of digital rights (hereinafter, LOPDGDD).

In addition, it should be borne in mind that although in the case raised in principle only the contact details are provided in order to be able to request the consent of the affected professionals to participate in a clinical trial, the context in which this communication takes place (these are contact details of people registered in a register of people affected by COVID 19) also involves the disclosure of health data.

For this reason, it must be borne in mind that, when the treatment affects special categories of data, as is the case with data relating to health (Article 4.15) RGPD), it is also necessary to have one of the authorizations established in Article 9.2 of the RGPD, in order to be able to consider this data processing lawful.

Article 9 of the RGPD provides that:

> "1. The processing of personal data that reveal ethnic or racial origin, political opinions, religious or philosophical convictions, or trade union affiliation is prohibited, and the processing of genetic data, biometric data aimed at uniquely identifying a natural person, data relating to the health or data relating to the sexual life or sexual orientation of a natural person.
>
> 2. Section 1 will not apply when one of the following circumstances occurs:
>
> (...)
> i) the treatment is necessary for reasons of public interest in the field of public health, such as protection against serious cross-border threats to health, or to guarantee high levels of quality and safety of health care and medicines or sanitary products, on the basis of the Law of the Union or Member States that establishes appropriate and specific measures to protect the rights and freedoms of the interested party, in particular professional secrecy.
>
> (…)"

Articles 6.1.e) and 9.2.i) of the RGPD, cited, enable the processing of personal data, including health data, by the competent authorities in matters of public health when the processing is necessary for reasons of public interest in the field of public health, as, for example, when there is a risk or a serious threat to the health of the population, as long as it is done on the basis of a rule with the rank of law that establishes appropriate and specific measures to protect the rights and freedoms of the people affected.

At the same time, the seventeenth additional provision of the LOPDGDD states that:

> "1. The treatments of health-related data and genetic data that are regulated in the following laws and their provisions are covered by letters g), h), i) and j) of article 9.2 of Regulation (EU) 2016/679 development:
>
> a) Law 14/1986, of April 25, General Health. (…)
>
> g) Law 33/2011, of October 4, General Public Health.
> (...).”

Law 18/2009, of 22 October, on public health (LSP), has as its object the organization of actions, benefits and services in the field of public health in the territorial scope of Catalonia established by the Law 15/1990, of July 9, of health regulations of Catalonia, to guarantee the monitoring of public health, the promotion of individual and collective health, the prevention of disease and the protection of health (article 1).

In accordance with this Law, epidemiological surveillance in public health consists of the collection, analysis, interpretation and dissemination of all information related to the appearance and spread of diseases and their determinants, with the aim to achieve effective control and give a quick response to alerts and public health emergencies.

For its part, Law 33/2011, of October 4, general public health (LGSP) establishes that "public health surveillance requires early warning and rapid response systems for the detection and evaluation of incidents , risks, syndromes, diseases and other situations that may pose a threat to the health of the population" (article 12.3).

For this purpose, the Epidemiological Surveillance Network of Catalonia is created (article 50 LSP and Decree 203/2015, of September 15) as a system of organization of relations for the exchange of health information and epidemiological surveillance based on the communication that is established between the different epidemiological surveillance services involved and the care network of Catalonia.

Specifically, it includes the bodies of the General Sub-Directorate for Public Health Surveillance and Response to Public Health Emergencies of the Public Health Secretariat of the department responsible for health, the Center for Epidemiological Studies on Sexually Transmitted Infections and AIDS of Catalonia (CEEISCAT), the Epidemiology Service of the Public Health Agency of Barcelona and the entire healthcare network in Catalonia, both public and private (article 3.3 Decree 203/2015).

One of the information systems maintained by the Epidemiological Surveillance Network of Catalonia is that of notifiable diseases, which receives notifications of notifiable diseases and epidemic outbreaks of any etiology from the healthcare network.

With regard, specifically, to Covid19, it has been planned that detected cases must be notified, urgently, to the corresponding territorial epidemiological surveillance service or to the SUVEC (outside working hours), and to the General Sub-Directorate of Surveillance and Response to Emergencies of the Public Health Agency of Catalonia (ASPCAT) (Procedure for action against cases of infection by the new SARS-CoV-2 coronavirus, available on Canal Salut).

In accordance with Law 5/2019, of July 31, of the Public Health Agency of Catalonia and amending Law 18/2009, of October 22, on public health, the ASPCAT aims provide the services of the Public Health Services Portfolio that correspond to the competent department in health matters (Article 2). The APSCAT is attached to the Department of Health through the Secretary of Public Health, which has the organic rank of general secretary.

As stated in the consultation, these data on probable or confirmed cases of infection by Covid19 (and, where applicable, contacts) notified in compliance with the provisions of Decree 203/2015, in connection with public health legislation, would consist of the Covid19 register for which the Department of Health would be responsible.

In accordance with the regulations examined, both the SUVEC and the ASPCAT or the Department of Health (like the rest of the members of the Epidemiological Surveillance Network of Catalonia) are authorized to process health data relating to people who have had positive results in tests for the detection of Covid19 (including, when appropriate, professionals in health centers), for the purposes of surveillance and epidemiological action in public health, which includes taking control and prevention measures to reduce its spread or incidence in the population (articles 6.1.e) and 9.2.i) RGPD).

Point out that, in accordance with Organic Law 3/1986, of April 14, on special measures in matters of public health, the competent authorities in matters of public health may "adopt measures of recognition, treatment, hospitalization or control when rational indications are appreciated that allow us to assume the existence of a danger to the health of the population due to the specific health situation of a person or group of people or because of the health conditions in which an activity is carried out" (article 2) and, for this to control communicable diseases, they can "adopt the appropriate measures for the control of the sick, of the people who are or have been in contact with them and of the immediate environment, as well as those considered necessary in case of risk of character transmissible" (article 3).

Forecasts that are also included in article 55.1.j) of the LSP.

IV

Having said that, it should be borne in mind that the health data that are collected for epidemiological surveillance in public health by the competent administrations and bodies in this field of action can be used later for research purposes.

In fact, in view of the provisions established in the applicable regulations, it can be said that research in this context would not cease to be data processing for the purposes of surveillance and response to public health emergencies.

It should be noted, in this sense, that article 8.1 of Law 14/1986, of April 25, general health (LGS), provides that "the carrying out of the epidemiological studies necessary to guide more effectively the prevention of health risks, as well as health planning and evaluation,

must have as a basis an organized system of health information, surveillance and epidemiological action."

Article 5.1.b) of the RGPD, relating to the principle of purpose limitation, provides that personal data must be collected "for specific, explicit and legitimate purposes, and will not be subsequently processed in a manner incompatible with said purposes ; in accordance with article 89, section 1, the subsequent processing of personal data for archival purposes in the public interest, scientific and historical research purposes or statistical purposes will not be considered incompatible with the initial purposes."

Article 9.2 of the RGPD, mentioned above, states that the prohibition to treat special categories of data will also not apply when:

> "j) the treatment is necessary for archival purposes in the public interest, **scientific** or historical research purposes or statistical purposes, in accordance with article 89, paragraph 1, **on the basis of the Law** of the Union or **of the Member States,** which it must be proportional to the objective pursued, essentially respect the right to data protection and establish appropriate and specific measures to protect the interests and fundamental rights of the interested party".

The fifth final provision of the LOPDGDD has added a new article 105 bis) to the LGS, according to which "the treatment of personal data in health research will be governed by the provisions of the seventeenth additional provision of the Organic Law of Protection of Personal Data and Guarantee of Digital Rights."

Thus, the seventeenth additional provision of the LOPDGDD is the internal law rule that regulates the processing of data for health research. Specifically, the second section provides that:

> "2. Data processing in health research will be governed by the following criteria:
>
> a) The interested party or, as the case may be, their legal representative may grant consent for the use of their data for the purposes of health research and, in particular, biomedicine. (…). b) **The health authorities and public institutions with powers to monitor public health may carry out scientific studies without the consent of those affected in situations of exceptional relevance and seriousness for public health.** c) The reuse of personal data for health and biomedical research purposes will be considered lawful and compatible when, having obtained consent for a specific purpose, the data is used for research purposes or areas related to the area in which the initial study was scientifically integrated.
>
> (…).
> d) The use of pseudonymized personal data for health and, in particular, biomedical research purposes is considered lawful.
> The use of pseudonymized personal data for the purposes of public health and biomedical research will require: 1.º A technical and functional separation between the research team and those who carry out the pseudonymization and keep the information that makes re-identification possible.

2.º That the pseudonymized data are only accessible to the research team when: i) There is an express commitment to confidentiality and not to carry out any re-identification activity. ii) Specific security measures are adopted to prevent re-identification and access by unauthorized third parties.

The re-identification of the data at its origin may be carried out, when due to an investigation that uses pseudonymized data, the existence of a real and concrete danger to the safety or health of a person or group of persons is appreciated, or a serious threat para sus derechos or necessary to guarantee adequate health care.

(…).”

Section 2.b) of the seventeenth additional provision of the LOPDGDD enables the processing of data for health research purposes without the consent of the affected whenever it is carried out by the health authorities and competent public institutions under the supervision of public health and only if there are circumstances of exceptional relevance and seriousness for public health.

In other words, it enables its treatment for those investigations that can be carried out within the framework of public health legislation (LGSP and LSP) by the health authorities and competent administrations in public health that have been assigned the function of surveillance and epidemiological action, with, where appropriate, the participation of the private sector.

It is known that we are currently in a public health emergency of international importance due to the SARS-CoV-2 (Covid19) coronavirus.

According to the information available, the research referred to by the DPD in its inquiry is a clinical trial that has been started by the public administration in Catalonia to treat the coronavirus, with the main objective, in large traits, to reduce contagion and stop the spread of the virus.

Specifically, the trial consists of prescribing one antiretroviral drug to people positive for the coronavirus and another to their contacts. In this way, the first drug aims to reduce the number of days during which the infected person has a viral load, while the other drug is expected to prevent the development of the disease in their contacts. Thus, by this double route, an attempt will be made to slow down the chain of transmission.

The Department of Health, other entities in the health field, the research team of Hospital B and pharmaceutical laboratories are participating in this clinical trial. The trial is coordinated by healthcare and public health professionals in the territories, and has the approval of the Spanish Medicines Agency and the World Health Organization.

In the information clause of the participation forms in the clinical study, the Department of Health is specifically stated as being responsible for the processing of the personal data necessary for the management of the aforementioned study.

Therefore, it seems clear both the exceptional gravity for public health reasons, and the consideration of authority in matters of public health of the person in charge of the treatment required by section 2.b) of DA 17a of the LOPDGDD.

This website also states that Hospital B is carrying out the clinical study in question.

As mentioned in recital 161 of the RGPD, scientific research activities in clinical trials are governed by their specific regulations, this is EU Regulation 536/2014, of April 16, on clinical trials of medicinal products human use and Royal Decree 1090/2015, of 4 December, which regulates clinical trials with medicines, ethics committees for research with medicines and the Spanish Registry of Clinical Studies.

Article 3.1.c) of RD 1090/2015 establishes that participation in this type of study requires the informed consent, freely expressed, of the test subject in the terms provided for in articles 4 to 8 of the same RD.

Therefore, at an initial moment of the clinical study, it is necessary to have the necessary information to contact the people likely to be part of the clinical trial, in order to offer them the possibility of participating- there

Bearing in mind that, based on the information available, the clinical study is promoted or initiated by the Department of Health, within the scope of the powers attributed to it in the field of public health surveillance by current legislation, as well such as the health emergency situation in which we find ourselves, the processing of data available to this Department in relation to people who have tested positive for Covid19 infection, for the purposes of
carry out the aforementioned clinical study, could be understood to be protected by the provisions of article 9.2.j) of the RGPD in relation to section 2.b) of the seventeenth additional provision of the LOPDGDD.

Given that, as we have seen, in this case the Department would count on Hospital B to develop or carry out the clinical trial, it could be admitted that the research team of this institution should be able to process this data available to the Department for the said purpose of clinical research in the field of public health.

For all that, the access to the data contained in the Covid19 register of the Department of Health by the research staff developing the clinical trial, with the purpose of recruiting patients for the clinical study started by the same Department, could result in the present case a lawful data processing, on the basis of article 9.2.j) of the RGPD in connection with section 2.b) of DA 17a of the LOPDGDD.

In any case, the Department of Health, as responsible for the treatment, according to the information available, should have established, with the other entities participating in the project that must process personal data, prior to the 'access to the data by these entities, an agreement or binding legal act for the commission of the treatment, with the content established in article 28.3 RGPD.

v

With regard to the possibility that the research staff of Hospital A could have access to this type of personal information for the purposes of clinical research, as proposed in the consultation, we believe that this could be possible if the conditions are met to which reference has been made.

That is to say, if, in the framework of the public health emergency situation in which we find ourselves, the health authorities and public institutions competent in monitoring public health started a scientific study, the material realization of which or the development of the same would fall to the research staff of Hospital A. This, without prejudice to bringing together the rest of requirements required by the applicable sectoral legislation.

In accordance with the considerations made so far in relation to the query raised, the following are made,

Conclusions

For the information available, the treatment of the data of people who have given positive results for infection by Covid19 available to the Department of Health for the performance of a clinical trial to deal with the exceptional situation in the field of public health generated by COVID19 could find legitimacy in article 9.2.j) of the RGPD in connection with section 2.b) of DA 17a of the LOPDGDD.

The communication of data by the Department of Health, responsible for the treatment, to Hospital B for it to develop the clinical trial on behalf of the Department should have formalized, before the communication of the data, through a processing order.

Access to this information by the research staff of Hospital A to carry out other similar studies would require the concurrence of the same circumstances.

Barcelona, April 27, 2020