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In this resolution, the mentions of the affected entity have been hidden in order to comply with art. 17.2 of Law 32/2010, given that in case of revealing the name of the affected entity, the physical persons affected could also be identified.

File identification

Archive resolution of the previous information no. IP 215/2020, referring to the Hospital (...)

Background

1. On 07/14/2020, the Catalan Data Protection Authority received a standardized form, completed by the Data Protection Officer (DPD) of the Hospital (...) (henceforth, H(...)), for which a security breach (NVS) was notified that would have occurred in that hospital. Specifically, the following was set out:

a) That at *"The Hospital (...) they offered him to participate in the STATE ASSESSMENT STUDY IMMUNITY FOR HEALTHCARE STAFF IN CATALONIA AGAINST THE SARS-COV2 VIRUS (VISCAT).*

This study assumed and according to the attached protocol; the transfer of data of the workers and cleaning staff and other activities that have been on the front line of the COVID-19 (see point 5 selection of participants of the document PROTOCOL FOR A VDEF PROJECT. In the protocol of the study the only requirements that provided (see page 6 of the power point VISCAT CENTRES PARTICIPANTS VDEF): bring it to the attention of the CEIm of the center to which it is attached, and inform its workers.

The Hospital (...) informed its workers of the study, but did not bring it to the attention of its CEIm".

We believe that the security breach exists in that the data of 3,056 people (names and surnames, electronic addresses and ID) have been transferred to CatSalut to participate in the study without the prior consent of those affected. Once the data was uploaded to the platform (see pages 7, 8 and 9 of the VISCAT CENTRES PARTICIPANTS VDEF powerpoint), this automatically sent an email to the worker to participate (where he had informed consent).

It is believed that the protocol of the study does not require prior consent to obtain the data from CatSalut , *since without consent, no legal basis has been found to legitimize the transfer. And in the event that he already had the data, he could not use it for a research study. So; and in my opinion, the transfer of data is not in accordance with the law; and there is an error in the study protocol, as it should require the consent of the interested party".*

b) That the data that the H(...) had communicated to the Catalan Health Service (CatSalut) - promoter of the cited study - were the *"name and surname, DNI and email* [corporate]" of 3,056 *"own workers".*

c) That the participation of H(...) in *"the study for the evaluation of the immune status of health personnel in Catalonia against the sars-cov2 virus (VISCAT); it remains in abeyance and stops until the ceim of the (...) reviews it".*

d) That *"we are considering whether to send an email to all those affected, that for the time being, the study is stopped as there is doubt about the legality in accordance with the regulatory framework on data protection, as long as the APDCAT corroborates that consent is necessary for the transfer of data".*

Together with the NVS form, various documentation related to the referred study, as it has progressed, promoted and financed by CatSalut, was provided, among others:

1) *"Protocol_per_a_projecte_vdef",* in which the following text is included:

> *"3. Objectives and purpose of the study*
>
> *To determine the percentage of healthcare personnel in Catalonia who have overcome SARS-CoV-2 infection in all areas of care and who have developed antibodies against SARS-CoV-2.*
>
> *Analyze the evolution of the immune status of these health personnel in the next 12 months.*
> *(...)*
> *8. Ethics and legal aspects*
> *(...)*
> *Healthcare staff will receive an email with a link to answer the health survey included in the protocol and give consent to participate in the study. Professionals must read the information sheet with the study protocol before giving consent".*

2) *"Procedures for action by participating centers",* with the following text:

> *1. Express adherence to the study:*
>
> *Participating centers must express their willingness to participate in the study by sending an e-mail to the microbiology laboratory that acts as a reference.*
> *Participating centers must bring the project to the attention of the CEIC of their center or the CEIC they refer to. They can indicate that the Vall d'Hebron University Hospital, coordinating center of the study, has already obtained the authorization of its CEIC, and adhere to it, if the corresponding CEIC considers it so or they do not have a CEIC.*
> *This process is prior and necessary before starting to join professionals in the study*

2. *"Publicize and inform your professionals about the study*

   The corresponding managers of the participating center must, through the usual means and mechanisms they have implemented, inform and publicize the study within their center among their professionals

   The communication must mention at least:

   Purpose and objectives of the study.

   Voluntary nature of your participation.

   Soon you will receive a link in your email to read and confirm the informed consent and the health survey and thus express your participation in the study."

2. By letter of 24/07/2020, the Authority informed the DPD of H(...) that its notification dated 14/07/2020, relating to H(...), it could not be considered a security breach but rather had the nature of a complaint, to the extent that it brought to the attention of this Authority alleged breaches of the data protection regulations by said entity in its capacity as responsible for the treatment of affected data; and that, for this reason, the investigation into said violation was considered complete, proceeding to initiate a phase of prior information in charge of the Inspection Area (no. IP 215/2020), in accordance with what is provided for in article 7 of Decree 278/1993, of November 9, on the sanctioning procedure applied to the areas of competence of the Generalitat, and article 55.2 of Law 39/2015, of 1 October, of the common administrative procedure of the public administrations (henceforth, LPAC), in order to resolve eventual responsibilities in relation to the facts reported.

In that same office, the DPD was required to report on what would be the legal basis that could legitimize the communication of the data of H(...) workers to CatSalut, in the absence of prior consent.

3.- On 07/26/2020, the DPD responded to the previous request, in writing stating the following:

"The design of the protocol did not mention that consent was requested for the transfer of data. Remember that the basis of all data transfers must be based on the prior consent of the interested party.

This consent is not foreseen in the protocol of the study, because we can say that it "incites" to commit security incidents by all the health centers that participate, and at the same time violate the rights of all the workers and third parties, who turn around the Catalan health centers.

Understanding and how explicitly this Authority echoes the current legal framework that names and surnames, ID and email addresses are personal data; health centers cannot transfer them to third parties without the prior consent of the interested parties, even if it is to be informed to participate in research studies. This data has not been processed by the health centers for this reason. Well, the protocol of the VISCAT study

had to provide for the prior consent of each health center for the transfer of data to CatSalut, so that it could report on the aforementioned study.
A possible legal basis - which is also unknown if it can be applied to it, as there are doubts as to whether it can fit into the Study for the evaluation of the immune status of healthcare personnel in Catalonia against the sars-cov2 virus -; it would be justified under the protection of the Seventeenth Additional Provision of the Organic Law on Data Protection and Guarantee of Digital Rights, 2.b) (...).
However, it is not known if it has a 100% match either by entity (CatSalut) or by nature and study. Despite everything, at no time did CatSalut (promoter of the study) justify this legal basis for the processing of the data. Only, that they were ceded without providing for the rights of the interested parties (workers)".

Along with this last letter, various documentation was provided, among others, the answer that *"Type Code. The Union Association of health and social entities"* had given to a query formulated by the DPD on 07/14/2020 linked to the processing of personal data in the aforementioned study.

Fundamentals of law

1. In accordance with the provisions of articles 90.1 of the LPAC and 2 of Decree 278/1993, in relation to article 5 of Law 32/2010, of October 1, of the Authority Catalan Data Protection Agency, and article 15 of Decree 48/2003, of February 20, which approves the Statute of the Catalan Data Protection Agency, the director of the Catalan Data Protection Authority.

2. As has been done in the background, it was reported that the H(...) would have communicated to CatSalut personal data (name and surname, ID and corporate email), so that said entity - promoter of *the "Study for the evaluation of the immune status of healthcare personnel in Catalonia against the sars-cov2 virus (VISCAT)"* - contacted these people in order to recruit them to participate in the aforementioned study. In this sense, the DPD of the H(...)
the complainant expressed his doubts that, in the absence of consent, there was another legal basis that would legitimize this communication.

Therefore, it is a matter of elucidating whether, in the absence of the workers' consent, there is another legal basis that legitimizes the communication of their data by the H(...) to CatSalut within the framework of the cited study.

Law 15/1990, of July 9, on the health system of Catalonia, creates CatSalut, a public body of an institutional nature, dependent on the Department of Health which, in accordance with article 3 of this rule, has as a *"ultimate objective is the maintenance and improvement of the health level of the population, through the development of the functions entrusted to it".* This same rule, regarding CatSalut, establishes the following:

Article 6
"Purposes

1 These are the purposes of the Catalan Health Service (...)

"h) The stimulation and support of scientific research in the field of health".

Article 7
"Functions

1 In order to achieve its goals, the Catalan Health Service, within the framework of the guidelines and priorities of the health protection and health care policy and the general criteria of health planning , performs the following functions: (...)

d) The management and execution of actions and institutional programs in matters of health promotion and protection, disease prevention, health and socio-health care and rehabilitation."

On the other hand, it is necessary to show that the H(...) is a private non-profit institution that provides public health services in concert with CatSalut, as it is part of the comprehensive health system for public use in Catalonia -SISCAT- (Decree 196/2010).

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 EC), as explicitly recognized in Article 8 of Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights (hereinafter, LOPDGDD).

Law 14/1986, of April 25, General of Health, recognizes in its article 8, as a fundamental activity of the health system *"the realization of the necessary epidemiological studies to orient more effectively the prevention of health risks, as well as health planning and evaluation, having as a basis an organized system of health information, vigilance and epidemiological action".* And, in the field of public health, Law 33/2011, general public health, defines *"public health"* as *"the set of activities organized by public administrations, with the participation of society, to prevent disease so* *how to protect, promote and recover people's health, both individually and collectively and through health, sectorial and transversal actions".*

Title II of the aforementioned Law 33/2011 establishes a series of public health actions that must be carried out by the health administrations, among which the one provided for in article 23.1.a must be highlighted):

"The Health Administrations will adopt the necessary measures so that the Assistance Services and those of public health, establish an effective coordination to develop the following actions:

a) Exchange the information necessary for public health surveillance and on the health situation and its social conditions for a better welfare action of the assigned community."

And article 41 of this same law provides for the following:

"Organization of information systems.
1. The health authorities in order to ensure the best protection of the health of the population may require, in the terms established in this article, reports, protocols or other documents for the purposes of health information from the health services and professionals.
2. The Health Administrations will not need to obtain the consent of the affected persons for the treatment of personal data, related to health, as well as their transfer to other Public Health Administrations, when it is strictly necessary for the protection of the health of the population .

3. For the purposes indicated in the two previous sections, public or private persons will transfer to the health authority, when so required, the personal data that are essential for decision-making in public health, in accordance with the established in Organic Law 15/1999, of December 13, on the Protection of Personal Data.

In any case, access to medical records for epidemiological and public health reasons will be subject to the provisions of section 3 of article 16 of Law 41/2002, of November 14, basic regulation of Patient Autonomy and Rights and Obligations in the field of Clinical Information and Documentation".

For its part, Law 18/2009, of October 22, on public health, determines the following:

Article 1
"Object
The purpose of this law is to organize the actions, benefits and services in the field of public health in the territorial area of Catalonia established by Law 15/1990, of July 9, on the health organization of Catalonia, by to guarantee the surveillance of public health, the promotion of individual and collective health, the prevention of disease and the protection of health, in accordance with

article 43 and those that agree with it of the Constitution, in the exercise of the powers that the Statute attributes to the Generalitat and in the framework of the legislation that regulates the health system of Catalonia, promoting coordination and col· collaboration of the bodies and public administrations involved within their areas of competence".

Article 2
"Definitions
For the purposes of the provisions of this law, it is understood by:
(...)
p) Public Health: organized set of actions by public authorities and society as a whole through the mobilization of human and material resources to protect and promote people's health, in the individual and collective sphere, prevent disease and take care of health surveillance.

(...)
r) Public health surveillance: the set of activities aimed at collecting, analyzing, interpreting and disseminating health data relating to living beings, food, water, the environment, products, activities and services, and also the health status of people considered collectively, with the aim of controlling diseases and health problems"

Although in the case presented the data that H(...) communicated to CatSalut were not health data, given the context in which this communication took place, it is not superfluous to collate here those rules that would constitute a sufficient legal basis to carry out the treatment of health data.

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.

(…)"

Article 9.2.i) of the RGPD enables 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 Organic Law 3/2018, of December 5, on the protection of personal data and the guarantee of digital rights (hereinafter, LOPDGDD) provides that:

"1. The treatments of health-related data and genetic data regulated by the following laws and their provisions of deployment:

a) Law 14/1986, of April 25, general health.
(...)
g) Law 33/2011, of October 4, general public health"

At this point, a specific mention should be made of the regime established in additional provision seventeen, in its section 2.b), regarding treatments in health research:

"Health authorities and public institutions with powers to monitor public health can carry out scientific studies without the consent of those affected in situations of exceptional relevance and seriousness for public health".

And to finish, it is not superfluous to point out that article 5.1.b) of the RGPD, relating to the principle of purpose limitation, provides that the data must be collected *"for specific, explicit and legitimate purposes, and will not be processed subsequently manner incompatible with said purposes; in accordance with article 89, paragraph 1, the subsequent processing of personal data for archiving purposes in the public interest, scientific and historical research purposes or statistical purposes will not be considered incompatible with the initial purposes".*

It goes without saying that the crisis generated by COV-19 has exceptional relevance and severity for public health. It should also be emphasized that the data communicated are data from people working in a hospital center - the H(...), which is part of the health network for public use - people who have been exposed more or less direct to the virus being, precisely, this exposure and its derivatives on the subject of the study that was the origin of the communication.

Consequently, and in view of the aforementioned rules, the consent of the affected persons would not be necessary for the transfer of personal data to Public Health Administrations for reasons of public health; and research, in this context, as he has considered this Authority in its opinion CNS 14/2020, given that *"it would not cease to be data processing for the purposes of surveillance and response to public health emergencies".*

3. In accordance with everything that has been set out in the 2nd legal basis, and given that during the actions carried out in the framework of the previous information it has not been accredited, in relation to the facts that have been addressed in this resolution, no fact that could be constitutive of any of the violations provided for in the legislation on data protection, should be archived.

resolution

Therefore, I resolve:

1. File the actions of prior information number IP 215/2020, relating to the Hospital (...)

2. Notify this resolution to the Hospital (...) .

3. Order the publication of the resolution on the Authority's website (apdcat.gencat.cat), in accordance with article 17 of Law 32/2010, of October 1.

Against this resolution, which puts an end to the administrative process in accordance with article 14.3 of Decree 48/2003, of 20 February, which approves the Statute of the Catalan Data Protection Agency, the denounced entity can file, with discretion, an appeal for reinstatement before the director of the Catalan Data Protection Authority, within one month from the day after its notification, in accordance with the which provides for article 123 et seq. of Law 39/2015. An administrative contentious appeal can also be filed directly before the administrative contentious courts, within two months from the day after its notification, in accordance with articles 8, 14 and 46 of Law 29/1998 , of July 13, governing the contentious administrative jurisdiction.

Likewise, the reported entity can file any other appeal it deems appropriate to defend its interests.

The director,