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Opinion in relation to a Hospital's inquiry about access to data from the Stop Covid19 Cat application of the Department of Health through the Agency's data analytics program for research and innovation in health (PADRIS) of Health Quality and Assessment of Catalonia (AQuAS) within the framework of a project research

A letter from a Hospital (hereinafter, the Hospital) is submitted to the Catalan Data Protection Authority, in which an opinion is requested from this Authority in relation to access to data from the Stop Covid19 Cat application, from the Department of Health, through the PADRIS program, for a research project.

The consultation explains that, from the Ethics Committee for Clinical Research with Medicines (CEIm) of the Hospital, a research project is being evaluated, in the context of COVID-19, which plans to use the data collected by the Department of Health through the Stop Covid19 Cat application, through the PADRIS program of the Quality and Evaluation Agency Sanitaires de Catalunya (AQuAS).

In this context, the consultation raises the following questions for this Authority:

"- If access by AQUAS to the data from the Stop Covid19 Cat app is legitimate based on the data controller contract with the Department of Health.

- If so, and it can be understood as legitimate access based on the previous argument, they can be used in the context of the PADRIS program for research purposes."

Having analyzed the request, which is not accompanied by more information, in view of the current applicable regulations, and the report of the Legal Counsel, the following is ruled.

I

(...)

II

The consultation explains that, as stated in the protocol of the research project in question, through the call for the PADRIS Program "PROCEDURE FOR PRIORITIZATION OF PROPOSALS FOR STUDIES RELATING TO SARS-COV-2 AND COVID-19", it is intended to access the data that AQUAS facilitates in the context of this program, which come from the data collected in the Stop Covid19 Cat app.

According to the consultation, within the evaluation process of the research project, AQUAS was consulted on the legitimating basis for access by AQUAS to the data of the Stop Covid19 Cat app, to which they responded, according to the consultation, that the treatment would be legitimized through the existing treatment manager contract between the Department of Health and the AQUAS. According to the inquiry, the AQUAS would have stated that this contract

provides access to SISCAT data and allows the necessary treatments to make them available to the scientific community.

Given the consultation in these terms, at the outset, it should be borne in mind that Regulation (EU) 2016/679, of the Parliament and of the European Council, of April 27, 2016, General Data Protection (hereinafter, RGPD), establishes that all processing of personal data must be lawful, loyal and transparent (article 5.1.a)).

The processing of data of natural persons who are users of the application is subject to the principles and guarantees of the personal data protection regulations (RGPD and Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights (LOPDGDD)).

To locate the question raised, it is necessary to refer to the information available on the website of the Department of Health (<https://canalsalut.gencat.cat/ca/salut-az/c/coronavirus-2019-ncov/stop-covid19-cat/>), where you can download the application for the purpose of "tracking and monitoring the symptoms of coronavirus."

In the section corresponding to the "conditions and privacy policy", of the "Note regarding the commissioning of new solutions for the prevention and control of SARS-CoV-2 infection", it is explained that "COVID19chat manages user information related to the impact of COVID19 to determine the evolution of the disease and plan actions and responses by the Health system."

According to the information available, the person responsible for the application is the Department of Health (although as we will see below, the privacy policy states that it is jointly responsible, it seems that it is necessary to understand that it is the only person responsible because in this privacy policy no other entity is indicated), and the intended purpose is: "Manage health, identification and geolocation data, to determine the evolution of the Covid19 disease, for research and statistics."

In the section corresponding to the "Privacy Policy", the following information is specified:

"In accordance with the provisions of Regulation (EU) 2016/679 of April 27 regarding the protection of natural persons in relation to the processing of their personal data (hereinafter the "Regulation") and in relation to the data that users enter we inform you that:

- Those jointly responsible for the processing of your data are the Department of Health (DS) with CIF S0811001G and address at Travessera de les Corts, 131-159 - Pavilion Ave Maria, 08028 Barcelona. You can contact the Data Protection Officer via dpd@ticsalutsocial.cat

- Your data will be processed for the following purposes:

- manage health, identification and geolocation data, optionally, to determine the evolution of the Covid19 disease at an individual and aggregate level, to design and implement measures and strategies to improve the quality of services and, where appropriate, the activation of emergency systems for the provision of health care.

- carrying out research in relation to the coronavirus;

- and the realization of both quantitative and qualitative disease evolution statistics.

- Your data will be kept for as long as is necessary to be able to manage your use of COVID19chat, and depending on the evolution of the epidemiological situation and in accordance with the instructions or guidelines of the health authority .
 - Your data will be processed for the development of profiles in relation to the evolution of your symptoms of COVID19 and the possible provision of urgent assistance.
 - Your data will be communicated to the health authorities and healthcare service providers, as the case may be, as well as those other legally determined recipients. Your data will not be transferred to any country outside the European Union.
 - You have the right to access your data, request the rectification of inaccurate data or, if applicable, request its deletion. As well as limiting its treatment, opposing and withdrawing consent to its use for certain purposes. You can exercise these rights through the email lopdcovid.sem@gencat.cat
- (...).”

III

The consultation refers to a flow of personal data that, like any treatment, must have a sufficient legal basis (art. 6.1 RGPD), either by the consent of the affected (art. 6.1.a) RGPD), or by some other of the circumstances listed in article 6.1. Among others, according to article 6.1.e) of the RGPD, 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 Article 8 of the LOPDGDD has come to recognize.

When the treatment affects special categories of data, specifically data relating to health (Article 4.15) RGPD), as would be the case at hand, it is also necessary to have one of the qualifications established in Article 9.2 of the RGPD, in order to be able to consider this data processing lawful, according to which:

2. Section 1 will not apply when one of the following circumstances occurs: (...)
- h) the treatment is necessary for the purposes of preventive or occupational medicine, evaluation of the labor capacity of the worker, medical diagnosis, provision of assistance or treatment of a health or social type, or management of health and social care systems and services, on the basis of the Law of the Union or of the Member States or by virtue of a contract with a health professional and without prejudice to the conditions and guarantees contemplated in section 3;
 - 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 6.1, in connection with article 9.2, sections h) ii) of the RGPD, enable the processing of personal data, including health data, by the Department of Health when the processing is necessary for the provision of healthcare assistance or treatment, or for reasons of public interest in the field of public health, such as, for example, when there is a risk or a serious threat to the health of the population, provided that do 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.

In the area of Catalonia, it is necessary to take into account Law 18/2009, of 22 October, on public health (LSP), which aims to organize actions, benefits and services in the field of health public in the territorial scope of Catalonia established by Law 15/1990, of July 9, on the health system of Catalonia, to guarantee the monitoring of public health, the promotion of individual and collective health, the disease prevention and health protection (Article 1). In the same sense, Law 33/2011, of 4 October, general public health (LGSP)).

It should be borne in mind that the intended purposes for the treatment of data obtained through the application are those of "Managing health, identification and geolocation data, to determine the evolution of the Covid19 disease at an individual and aggregate level , to design and implement measures and strategies to improve the quality of services and, where appropriate, the activation of emergency systems for the provision of health care. Also the possible carrying out of research in relation to the coronavirus and the carrying out of both quantitative and qualitative statistics on the evolution of the disease."

In fact, the Stop Codiv19 Cat application asks users for identification through the Personal Identification Code (CIP) contained in the health card of users of the public health service. It is, therefore, data from people who are patients of the public health services in Catalonia.

As explained in the information available on the application: "The health system monitors your case based on the data sent by the application and, if necessary, activates emergency medical services."

The purpose of health care and research are therefore purposes foreseen in the application Stop Codiv19 Cat, which would be legitimized under the terms of the regulatory framework examined (articles 6.1.e) and 9.2.i) of the RGPD, in connection with the aforementioned health regulations and the provisions of the autonomy legislation of the patient (Law 21/2000, of December 29, on the rights of information concerning the patient's health and autonomy, and clinical documentation, and Law 41/2002, of November 14, basic regulation of autonomy of the patient and rights and obligations regarding information and clinical documentation).

IV

According to the information available (www.aquas.gencat.cat), the PADRIS Program, led by the Health Quality and Assessment Agency of Catalonia (AQuAS) of the Department of Health, "has the mission of making available to the scientific community related health data to promote research, innovation and evaluation in health through access to the reuse and cross-referencing of health data generated by the comprehensive health system for public use of Catalonia (SISCAT)".

Through Resolution SLT/570/2015, of March 16, which makes public a management order formalized by the Department of Health, the Catalan Health Service and the Catalan Institute of Health with the Health Quality and Evaluation Agency of Catalonia. (DOGC, no. 6843, April 1, 2015), the processing task to the AQuAS for the anonymization of the information included in files containing personal data of the Department, the ICS and the CatSalut, for the purposes specified in said Resolution (among others, research purposes), and its subsequent use and transfer of information for said purposes (Annex 2 of the Resolution).

In section 2 of the Manifestations of Resolution SLT/570/2015, it is foreseen that "The healthcare data of the health system of Catalonia are included in duly formalized personal data files, which are integrated in the scope of the Department of Health, the Catalan Health Service and the Catalan Institute of Health", files that are listed and specified in Annex I of the Resolution, to which we refer, among which are , among others, the Registry of specific pathologies and monitoring of health activities, the Registry of patient health information, the health status file, as well as the Registry of the minimum basic set of data.

At the outset, it seems clear that some of these personal data records and files are the responsibility of the Department of Health, the ICS and CatSalut (and that they are the source of the information managed by AQuAS in the PADRIS Program, through a processing order), may incorporate personal data that the Department of Health has obtained through the application to which the query refers, for assistance, public health and also research purposes.

However, beyond the specific records or "files" mentioned, which formally list the task of treatment (Annex 1 of Resolution SLT/570/2015), it should be borne in mind that with the full applicability of the RGPD, in automated treatments what is relevant when determining the information affected by the processing order will not be the concept of file, which is now not required to be formally created or notified to the data protection authorities, but the purpose for which the Department of Health, ICS and CatSalut process the data. And it is obvious that the care and research purposes for which the data is collected through the Stop Codiv19 Cat application fit within the data provided for in the above-mentioned order for treatment at AQUAS.

The purposes that enable data processing (medical assistance purposes (art. 9.2.h) RGPD) and purposes of public interest in the field of public health (art. 9.2.i) RGPD), as has been said , which allow it to be considered that AQuAS can access and process the data subject to consultation under the terms and conditions provided for in the order for the intended treatment.

At this point, it is appropriate to take into account the type contract model for the data controller that approved Resolution SLT/570/2015, it predates the entry into force of the RGPD (art. 99 RGPD). However, even though the order contract predates the full applicability of the GDPR, this does not mean that this order contract has lost its validity.

In this regard, the fifth transitional provision of the LOPDGDD provides for the following, in relation to previously signed treatment commission contracts:

"The data processor contracts signed prior to May 25, 2018 under the provisions of Article 12 of Organic Law 15/1999, of December 13, on the Protection of Personal Data will remain in force until expiration date indicated in them and in the event of an indefinite agreement, until May 25, 2022.

During these periods, any of the parties may require the other to modify the contract so that it complies with the provisions of Article 28 of Regulation (EU) 2016/679 and Chapter II of Title V of this law organic."

The Sixth Pact of Resolution SLT/570/2015 provides that the management assignment has an indefinite nature as long as none of the reasons for resolution established in the Seventh Pact of the same Resolution occur.

Therefore, in principle, based on the information available, the contract for the treatment that the Department of Health, as well as the ICS and CatSalut as responsible, would have signed with the AQuAS, for the data processing of the files and records set out in the aforementioned Resolution, in principle it would be valid until the aforementioned date (May 25, 2022), so it could enable access and treatment by AQuAS, as responsible, to the data of what PADRIS has, among others, if applicable, those from the Stop Covid19 Cat application, so that they can be treated and used for research purposes in relation to this health emergency.

This, without prejudice to the convenience that, as also provided for in the fifth transitional provision of the LOPDGDD, any of the parties, either those responsible for the processing of the data (Department of Health, ICS and CatSalut), or the AQuAS as to the person in charge of the treatment, demand the modification of the contract that was signed at the time, in order to foresee the relevant modifications in order to adapt its content to the provisions of article 28.3 of the RGPD.

v

Regarding the second question asked, that is, if, given the legitimate access of AQUAS to the data obtained with the application, this data can be used in the context of the PADRIS program for research purposes, it should be taken into account that the Program PADRIS has the main purpose of allowing the Research Centers of Catalonia (CERCA), the Research Centers linked to the public or non-profit care centers of the Integral System of Public Use of Catalonia (SISCAT), and the Universities belonging to the Catalan Association of Public Universities (ACUP), as can be seen from the information available on the PADRIS Program (specifically, in the document "Public data analytics program for research and innovation in health in Catalonia - PADRIS –", available on the website of the Department of Health), can access and process information from PADRIS for research purposes.

Taking this into account, AQuAS can offer the data to which it has access and which it treats as a person in charge based on the PADRIS Program to the various recipients of said Program for the intended purposes, provided that the conditions established in the order of the established treatment, and in accordance with the conditions determined by the Department of Health, as responsible for the treatment.

In this sense, and for the purposes of the research projects in which these data are intended to be used, it will be necessary to take into account, especially the provisions of the second section of the seventeenth additional provision of the LOPDGDD.

In accordance with the considerations made in this opinion in relation to the query raised, the following are made,

Conclusions

The data obtained through the Stop Covid19 Cat application for the purposes of health care and medical and epidemiological research, from users of the health system, may be subject to treatment by AQuAS through the order of treatment provided for in Resolution SLT/570/2015.

AQuAS can offer the data to which it has access and which it processes on the basis of the PADRIS Program to the various recipients of said Program for the intended purposes, as long as the conditions established in the treatment order are met, and in accordance with the conditions determined by the Department of Health, as responsible

Barcelona, May 28, 2020

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