CNS 18/2019

Opinion in relation to the consultation of an association in the health sector on different aspects related to section 2 of the seventeenth additional provision of Organic Law 3/2018, of December 5, on the protection of personal data and the guarantee of digital rights

A letter from an association in the health sector (hereinafter, the Association) is submitted to the Catalan Data Protection Authority in which a report is requested to this Authority on various issues related to the seventeenth additional provision of the Law organic law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights (LOPDGDD).

Specifically, the consultation asks about the definition of the term "health research" and the types to which the seventeenth additional provision of the LOPDGDD could be applied (epidemiological, observational, retrospective studies...). It also asks about the differentiation between "health research purposes" and "public health research purposes" for the purposes of applying this rule. Finally, and on how to inform the affected people through the center's corporate websit

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

I

(...)

II

According to the consultation, the purpose of the Association is the organization of activities and programs aimed at the promotion of mental health, prevention of mental illnesses, addictions and health education and, to achieve these objectives, performs tasks of psychiatric assistance and related to addictions, through reception, diagnosis, treatment, rehabilitation and social insertion activities.

The Association asks several questions in relation to additional provision 17a of the LOPDGDD (hereinafter, DA 17a), specifically:

> **"1. First of all, the definition, for the purposes of the data protection law, of the term "health research" is of interest. In other words, what type of research would be included in the application of DA 17ª? In particular, would it apply to epidemiological, observational, retrospective studies...?".**
>
> **2. (...) is there a difference between the concept of research in health and research in public health? It must be understood that health research refers to private research (public entities, concerted...) and public research is that carried out by health authorities and public institutions (referring to letter b) of the section 2 of DA 17ª?". If it is determined that there is a difference, this means that the requirem**

arise through the second paragraph of letter d) only apply to research in public health?".

3. Thirdly, the query asks what can be understood by "an easily accessible place on the corporate website of the center where the research or clinical study is carried out" (section 2.c) of DA 17a).

Based on the consultation in these terms, we start from the basis that, according to article 4.1 of Regulation (EU) 2016/679, of April 27, general data protection (RGPD), personal data is "all information about an identified or identifiable natural person ("the interested party"); Any person whose identity can be determined, directly or indirectly, in particular by means of an identifier, such as a number, an identification number, location data, an online identifier or one or more elements of identity, shall be considered an identifiable physical person physical, physiological, genetic, psychological, economic, cultural or social of said person;

The processing of data (art. 4.2 RGPD) of natural persons who receive assistance in health centers such as that formulated by the consultation is subject to the principles and guarantees of the personal data protection regulations (RGPD and LOPDGDD). We note that the principles and guarantees of data protection are fully applicable to pseudonymised data which are, for all intents and purposes, personal data (recital 26 and art. 4.5 RGPD).

The health care that patients receive in health centers involves the processing of health data (art. 4.15 RGPD) of these people ("interested persons", ex. art. 4.1 RGPD) and, therefore, it is necessary to take into account that information relating to the health of natural persons is subject to special protection.

Article 9 of the RGPD establishes the general prohibition of the processing of personal data of various categories, among others, data relating to health and genetic data (section 1). Section 2 of the same article 9 provides that this general prohibition will not apply when certain circumstances occur.

Among others, according to article 9.2.j), data processing would be enabled when: "j) the treatment is necessary for archival purposes in public interest, scientific or historical research purposes or statistical purposes, in accordance with the article 89, section 1, on the basis of the Law of the Union or of the Member States, which must be proportional to the objective pursued, essentially respect the right to data protection and establish adequate and specific measures to protect the interests and fundamental rights of the interested party".

According to article 89.1 of the RGPD:

"1. The treatment for archival purposes in the public interest, scientific or historical research purposes or statistical purposes will be subject to adequate guarantees, in accordance with this Regulation, for the rights and liberties of the interested parties. These guarantees will require that technical and organizational measures are available, in particular to guarantee respect for the principle of minimization of personal data. Such measures may include pseudonymization, provided that in that way said ends can be achieved. As long as those goals can be achieved through further processing that does not allow or no longer allows the identification of the interested parties, those goals will be achieved in that way."

From the perspective of the principle of purpose, according to article 5.1.b) of the RGPD, personal data must be collected "for specific, explicit and legitimate purposes, and will not be subsequently treated in a manner incompatible with said purposes ; in accordance with article 89, section 1, the further 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 ("limitation of the purpose") ;"

As follows from article 9.2.j), in connection with article 89.1 of the RGPD, in certain circumstances and taking into account the principles and obligations of data protection, personal data may be processed for a purpose general "scientific or historical research", purpose which may include, among others, scientific research in the field of health, as is clear from the RGPD itself, which refers specifically to the field of health (among others, in recitals 52, 53, 156, 157 or 159).

According to article 9.2.j) of the RGPD, the processing of data for scientific research purposes must be carried out "on the basis of the Law of the Union or of the Member States". DA 17a of the LOPDGDD is the internal law rule that regulates the processing of data for health research.

The fifth final provision of the LOPDGDD has added a new article 105 bis) to Law 14/1986, of April 25, general health (LGS), according to which: "The treatment of personal data in the investigation in health will be governed by the provisions of the seventeenth additional provision of the Organic Law for the Protection of Personal Data and Guarantee of Digital Rights."

Article 16.3 of Law 41/2002, of November 14, basic, regulating patient autonomy and rights and obligations in the field of clinical information and documentation, modified by the ninth final provision of the LOPDGDD, provides for access to medical history, among others, for research purposes.

III

Based on the aforementioned regulatory framework, we refer to the first question posed:

"1. First of all, the definition, for the purposes of the data protection law, of the term "health research" is of interest. In other words, what type of research would be included in the application of DA 17ª? In particular, would it apply to epidemiological, observational, retrospective studies...?".

Section 2 of DA 17a, which is the section of this article referring to research, establishes different criteria that must govern the processing of data in "health research", in the following terms:

"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 it

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: (...). (…).”

As the Article 29 Working Group points out, in the document "Guidelines on consent in the sense of Regulation (EU) 2016/679":

"The term "scientific research" is not defined in the RGPD. Recital 159 states "(...) The treatment of personal data for the purpose of scientific research must be interpreted, for the purposes of this Regulation, in a broad way (...)", however, GT29 considers that the notion must not expand beyond its common meaning and understand that "scientific research" in this context refers to a research project established in accordance with the corresponding methodological and ethical standards related to the sector, in accordance with appropriate practices."

A simple reading of letter j) of article 9.2 of the RGPD and, especially of the second section of DA 17a, allows us to conclude that it is a series of provisions referring to any type of investigation in health that requires the processing of health data, although after that, certain provisions applicable to different types of research are included.

The letters a) c), d) e) and f) refer generally to any type of research with health data, although they then refer specifically to biomedical research (“research purposes in health, and, in particular, biomedicine"). This does not mean, however, that these predictions should be applied only to biomedical research, but to any type of research.

Therefore, these forecasts include the different types of research provided for in Law 14/2007, of July 3, on biomedical research (LIB), but also other types of research that are excluded from the scope of application of the LIB, such as observational studies (art. 58.2 of the Guarantees and Rational Use of Medicines and Health Products Act of 2015 (Royal Legislative Decree 1/2015, of July 24)) or clinical trials, in which the LIB does not apply, and which, as stated in recital 161 of the RGPD, are regulated by its specific regulations (EU Regulation 536/2014, of April 16, on clinical trials of medicinal products for use human).

The same consideration can be made regarding the processing of personal data in relation to epidemiological studies, which are "fundamental activity of the health system" (eg art. 8.1 LGS), which is expressly provided for in the patient autonomy legislation (art. 16.3 Law 41/2002 and art. 11.3 Law 21/2000), as well as in other applicable regulations (among others, articles 50.2 and 83.2 LIB and art. 8 LGS).

On the other hand, letter b) of the second section of the DA 17a, refers to the investigation carried out by the health authorities and public authorities with powers in matters of public health in situations of particular relevance and gravity.

The provisions of DA 17a LOPDGDD are applicable, with the specificities provided for in each case, to all these types of health research. Without prejudice to the fact that there are different types of health research, any treatment (art. 4.2 RGPD) of personal health data, genetic data (art. 4.13 RGPD), or other categories of data, that is carried out under the terms of provisions of the Law of the Union or of the Member States (art. 9.2.j) and art. 89.1 RGPD), for research purposes (art. 5.1.b) RGPD) related to the health of people and the population in general, is subject to the application of the principles and guarantees of the data protection regulations , as the regulations make clear (article 16.3 of Law 41/2002, and article 105 bis) LGS).

IV

Having said that, we refer to the second question posed:

"2. (...) is there a difference between the concept of research in health and research in public health?. It must be understood that health research refers to private research (public entities, concerted...) and public research is that carried out by health authorities and public institutions (referring to letter b) of section 2 of DA 17ª?". If it is determined that there is a difference, does this mean that the requirements that arise through the second paragraph of letter d) only apply to research in public health?"

The query asks if "it should be understood that research in health refers to private research (private entities, concerted...) and public research is that carried out by health authorities and public institutions (referring to letter b) of section 2 of DA 17)?".

This Authority cannot share the interpretation indicated by the consultation, since, as we shall see, the regulations do not establish that research in public health is exclusively carried out by the public sector. On the contrary, the regulations applicable to health research provide for the collaboration and interrelationship of the public and private sectors in this area. The distinction between health research and public health research referred to in letter b) of section 2 of DA 17a does not depend on the nature of the subject that carries it out. Thus, the RGPD establishes that the processing of personal data for the purposes of scientific research and, therefore, also of health research, includes, among others, research financed by the private sector (Recital 159 RGPD). The participation of the private sector is also apparent from the preamble of the LIB and from article 83.4 of this Law.

In relation to this, we remember that the RGPD supports the processing of special categories of data for the development of research, particularly in the health field, with some flexibility. This is reflected in recitals 52 and 53 of the RGPD, applicable to all health research, not only to that carried out from the public sector, but also from the private sector.

Regarding this, Opinion 3/2019, on "Questions and Answers on the interrelationship between the regulation of clinical trials and the RGPD", of January 23, 2019, of the European Data Protection Committee, which examines the different legal bases that can enable the processing of data in clinical trials, admits that the legitimate interest of the person in charge (art. 6.1.f) RGPD) can be a legal basis that enables the processing, in this case, for the health research carried out from the private sector.

The key element for the distinction between health research and public health research is not the subject but the object of the research.

Specifically, to determine which research can be considered as public health research, we will have to take into account the concept of "public health" which is given to us both by the RGPD itself and by the legislation on public health.

According to Recital 54 of the RGPD:

"The treatment of special categories of personal data, without the consent of the interested party, may be necessary for reasons of public interest in the field of public health. This treatment must be subject to appropriate and specific measures in order to protect the rights and freedoms of individuals. In that context, "public health" must be interpreted in the definition of Regulation (EC) no. 1338/2008 of the European Parliament and of the Council, that is to say, all the elements related to health, specifically the state of health, including morbidity and disability, the determinants that influence said state of health, the needs of assistance health care, the resources allocated to health care, the provision of health care and universal access to it, as well as the costs and financing of health care, and the causes of mortality. This treatment of health-related data for reasons of public interest must not result in third parties, such as employers, insurance companies or banking entities, processing personal data for other purposes."

Thus, the concept of public health that incorporates the RGPD, in the terms provided for by EU Regulation 1338/2008, refers to various areas related to the health of the population (state of health and determinants that influence it, morbidity, disability ...), whose research is of public interest and brings a benefit to society as a whole.

In this sense, article 1 of Law 33/2011, of October 4, General Public Health (LGSP), in its second paragraph, defines what must be understood by public health:

> **"Public health is the set of activities organized by public administrations, with the participation of society, to prevent disease as well as to protect, promote and recover people's health, both individually and collectively and through health, sectoral and transversal actions."**

In short, given these and other regulatory provisions, the concept of "public health" encompasses a very broad set of activities in the field of research, which is not only limited to those carried out by the public sector (health authorities or public institutions), but involves the participation of both the public and private sectors, in the terms provided for in the aforementioned regulations.

According to the consultation, the different mentions of research "in health" and research "in public health" that is made in section 2 of Day 17a, could be very relevant, since it could lead to the requirements of the second paragraph of letter d) or the provisions of letter g) of Day 17a, must be applied only to "public health research".

Additional provision 17a contains three references to the concept of public health:

a) First of all, section 2.b) enables the processing of data without the consent of the affected whenever it is carried out by the health authorities and public institutions competent in public health surveillance, only if there are exceptional circumstances relevance and severity for public health.

It is clear that this section is referring to the concept of public health in the terms noted before that are derived from the LGSP. This would include the investigation carried out by a public authority, in particular, the health authorities assigned the function of surveillance and epidemiological action (art. 8.1 LGS and art. 41 LGSP), with or without the participation of the private sector .

b) On the other hand, with respect to the references to "public health" contained in letters d), f) and g), it seems that if a systematic interpretation is made of the entire precept, they would not refer only to the investigations that can be carried out carried out under the LGSP but any health research, such as research under the LIB, observational studies or clinical trials.

At the outset, it should be noted that the second section of DA 17a refers to health research. Generally. On the other hand, letter d), in its first paragraph, refers to "health research, and in particular, biomedical research". On the other hand, the second paragraph does not refer to "health research" but to "public health research".
This second paragraph must be read in conjunction with the first.

On the other hand, taking into account the data protection regulations (article 9.2.j), in connection with article 89.1 RGPD), as well as the sectoral regulations (art. 16.3 Law 41/2002), it must be understood that these assumptions of section 2 of DA 17a, refer to health research or biomedical research in general.

Limiting the application of the requirements of section 2.d), 2.f) or 2.g) of DA 17a only to the processing of data for research carried out by public sector officials, would be equivalent to emptying the content not only the provisions of these sections, but, by extension, of other legal requirements, such as that relating to the carrying out of a privacy impact assessment, which is a requirement of the RGPD itself (art. 35 RGPD), which is specified in section 2.f) of DA 17a).

By application of the data protection regulations, the data controller must articulate the technical and organizational measures necessary to guarantee, among others, respect for the principle of minimization of personal data (art. 5.1.c) RGPD) and to avoid the risk of re-identification of the information in the terms provided for in the RGPD and, given the reference to the law of the States of article 9.2.j), in section 2 of DA 17a, sections d), f) g).

v

Finally, in relation to the provision of DA 17a, section c), to provide information in a place "easily accessible from the center's corporate website", the consultation asks the following:

"Understanding that those affected must be notified of the existence of this information, which could be done by informing them generically and providing the URL where the complete information is found (layer system), it would be correct that this URL would it be found in a submenu of the website about the services that are performed at our institution in a section of "Research" or should it be announced (obviously) on the home page of the i

According to section 2.c) of DA 17a of the LOPDGDD:

> **"c) The reuse of personal data for health and biomedical research purposes will be considered lawful and compatible (...).**
>
> **In such cases, those responsible must publish the information established by article 13 of Regulation (EU) 2016/679 (...), in an easily accessible place on the corporate website of the center where the clinical investigation or study is carried out, and, in its case, in that of the promoter, and notify the existence of this information by electronic means to those affected.**
> **When these lack the means to access such information, they may request its referral in another format. (…).”**

This section provides for the possibility of reusing personal data for health and biomedical research purposes, without the need to obtain the consent of those affected. The LOPDGDD thus enables the processing of data that would have been initially collected for a specific purpose with the consent of those affected (see, in this regard, the sixth transitional provision of the LOPDGDD).

In this case, it is necessary to provide those affected with the information provided for in article 13 RGPD through the responsible person's website. This duty to inform those affected regarding the reuse of their health information (section 2.c) DA 17a) falls on the data controller (4.7 RGPD).

(...)

From the information available, it seems that the Association formulating the consultation would be part of a wider Health Care Group, which integrates other entities (...).

However, it is not known whether the treatment consisting of the reuse of personal data for research purposes, subject to the RGPD and the LOPDGDD, is carried out solely by the Association that formulates the query, or also by other entities which are part of the CHM Group. It is therefore unknown, in the case at hand, who would be responsible for the processing of personal data for research purposes.

In any case, without prejudice to the fact that in the case of data reuse, section 2.c) of DA 17a enables the person in charge to provide information through the web, the information that is transmitted must comply with the requirements of clarity and transparency of personal data protection regulations, as highlighted by the Article 29 Working Group in the document "Guidelines on transparency in the sense of Regulation (EU) 2016/679".

Thus, according to recital 39 of the RGPD: "For physical persons it must be completely clear that they are collecting, using, consulting or otherwise treating personal data that concern them, as well as the extent to which said data is or will be treaties The principle of transparency requires that all information and communication relating to the treatment of said data be easily accessible and easy to understand, and that simple and clear language be used. This principle refers in particular to the information of the interested parties about the identity of the person responsible for the treatment and the purposes thereof (...).”

Therefore, the information that is incorporated into the corporate website subject to consultation must allow those affected to clearly identify the person responsible for the treatment, whether the Association or, where appropriate, the other entities of the Group of care centers referred to in the query

Taking into account that, from the information available, the corporate website to which the query refers includes not only the Association, but other entities, and that it is not clear which of these entities are responsible for the processing of data for for research purposes, it would initially be necessary, for the purposes of complying with the principle of transparency, for users to be able to clearly identify the data controller.

Beyond that, given the information provided, this Authority cannot determine whether it would be sufficient to include the information in a submenu of the website ("Research" section), to which the query refers, or if it is necessary that the information be find visible on the home page of the institutional portal. Both options can be adjusted to the requirements of the RGPD, as long as those affected can easily locate the information and identify, with equal clarity, the person responsible for the treatment.

The query also asks, "In the event that it was considered that it should be evident at the start of the institutional portal, how long could it be considered lawful to have it referenced or announced (with a URL that leads to the complete information) considering that this part of the plain is normally used to announce informative aspects of the institutional activities carried out?".

Given that section 2.c) of DA 17a, allows the data controller to inform those affected by incorporating the information from article 13 of the RGPD on the corporate website, this information must necessarily be available and accessible by to those affected throughout the life cycle of the data processing itself, in this case, the reuse of health data for research purposes.

Thus, the maintenance of information on the corporate website, in a clear and easily accessible way for those affected, while the data is being processed, is not only "lawful" (as the query points out), but is a requirement of the data protection regulations, in application of the principle of transparency.

In this regard, it may be of interest to consult the Guide for the fulfillment of the duty to provide information in the RGPD (http://apdcat.gencat.cat/ca/documentacio/guies_basiques).

Finally, we agree that compliance with the duty of information in the terms set out is not the only specific requirement that section 2.c) of DA 17a provides in relation to the reuse of health data in those cases where an initial consent was already available. Thus, this section also requires as a requirement, in these cases, that the person in charge of the treatment has the approval ("prior favorable report") of the corresponding research ethics committee.

In accordance with the proposed query, the following are made,

Conclusions

By application of the regulations (art. 9.2.j) and art. 89.1 RGPD), section 2 of DA 17a is the internal law rule that regulates the processing of data for health research purposes, and is therefore fully applicable to any type of health research (with the specificities foreseen therein).

The reference to "public health" contained in letter b) of section 2 of DA 17a, must be understood as referring to research carried out within the framework of the LGSP. Instead, the provisions of letters d) f) ig) must be understood as referring to any health research.

The information that the person in charge incorporates into the corporate website for the purposes of complying with article 13 of the RGPD must be available in a clear and easily accessible manner for those affected, throughout the life cycle of data processing, on demand of the principle of transparency.

Barcelona, May 14, 2019