

PD 15/2020

Report on a Proposal for an article to be included in a Decree-Law to create the Vaccination Register of Catalonia

Background

The Department of Health asks this Authority to issue, as a matter of urgency, a report on a proposal for an article to be introduced in a Decree-Law on the creation of the Vaccination Register of Catalonia in the Department of Health.

Specifically, the wording of the proposal is as follows:

"Article (X)

Vaccination register of Catalonia

1. In order to exercise the powers attributed to it in the field of prevention and control of communicable infectious diseases and epidemic outbreaks, and public health surveillance, the Public Health Secretariat of the Department of Health must have the data relating to vaccination against COVID-19 and other vaccines for immunopreventable diseases in a treatment owned by you. Specifically, this data processing must allow surveillance and monitoring of the COVID-19 vaccination strategy to be carried out and to know the evolution of coverage, including the entire target population that is being incorporated.

For these purposes, centers and health services authorized for the administration of vaccines and those established as vaccination centers within the framework of the COVID-19 vaccination strategy must make available to the Department of Health the variables related to the following vaccination actions: data related to the identification of the recipients of the vaccines, data related to their administration, including: data related to the identification of the professionals who administer them, the identification of the center where they are administered, the data relating to the vaccination record (antigen, date of administration, batch, product supplied, manufacturing laboratory and national code of the product), as well as other data established by the health authorities. In the case of the vaccine against COVID-19, the non-administration must be recorded including any of the following variables: the non-supply of the vaccine due to the free decision of the recipient or his legal representative; the non-supply of the vaccine due to the existence of contraindications for its administration, indicating whether the contraindication is temporary or indefinite; or, the non-supply of the vaccine to be in a situation of immunity.

These data are included in the "Vaccination Registry of Catalonia" treatment, which is owned by the Department of Health.

2. The incorporation of the data in the "Catalan Vaccination Register" will be carried out:

a) In the case of centers and health services of the Comprehensive Health System of Use Public Administration of Catalonia (SISCAT), as well as other entities that provide health services on behalf of the Catalan Health Service, by incorporating the data indicated in section 1 of this article into their information systems own and the communication to the shared Clinical History of Catalonia using the integration routes available according to the instructions of the Department of Health, from where it will be integrated into the "Vaccination Registry of Catalonia".

b) Health centers and services not included in letter a) must incorporate the data related to the vaccination of paragraph 1 of this article through the systems made available by the Department of Health, with the greatest immediacy possible and , in any case, in a period not exceeding five calendar days from the date of administration of the vaccination. In the case of actions related to vaccination against COVID-19, the data must be incorporated within 24 hours from the time the vaccine is administered, waiver is formulated, or contraindication or immunity is established .

3. The information from the "Vaccination Register of Catalonia" originating from health centers and services not included in letter a) of section 2 of this article must be incorporated into the Shared Clinical History of Catalonia whenever the person to whom the vaccines have been administered, or their legal representative, has previously given their express consent. In the case of actions related to vaccination against COVID-19, the variables relating to the waiver of vaccination, the finding of contraindication or immunity, as appropriate.

In these cases, the center or health service must send the document of consent to the Secretary of Public Health of the Department of Health so that the incorporation of the information related to the vaccination performance in the "Registre de vacunació de Catalunya" becomes effective.

4. The persons who, in the exercise of the functions attributed to them, access the data established in section 1 of this article, remain subject to the duty of confidentiality.

5. The actions regulated in this article must comply with the requirements of the personal data protection regulations, the public health regulations as well as the regulations governing patient autonomy and rights and obligations in terms of information and clinical documentation."

Having analyzed the Project, which is accompanied by a report justifying the proposal, taking into account the current applicable regulations, and in accordance with the report of the Legal Adviser, I issue the following report:

Legal Foundations

I

(...)

II

In accordance with article 6 of the RGPD, in order to carry out personal data processing, one of the legal bases of article 6.1 must be met. Among the legal bases provided for, in the case we are dealing with would be the one provided for in letter e), referring to those cases in which the treatment is necessary for "for the fulfillment of a mission carried out in the public interest or in the exercise of powers public given to the person in charge of the treatment;".

On the other hand, the processing of health data for the purposes of healthcare and public health or for the prevention of occupational risks could be authorized by letters h) ii) of article 9.2 RGPD.

In accordance with the provisions of these articles, the legal basis must be established in the law of the member state that applies to the person in charge or the law of the European Union which, in any case, must determine the purpose of the treatment. With regard to the quality of this rule, it must fulfill an objective of public interest and must be proportional to the aim pursued (art. 6.3 if).

Regarding the scope of the internal law rule, Recital 41 RGPD establishes that "When this Regulation makes reference to a legal basis or a legislative measure, this does not necessarily require a legislative act adopted by a parliament, without prejudice to the compliance requirements of the constitutional order of the Member State in question.".

It should be taken into account in this respect that, in Spanish law, the rule that establishes the treatment must be a rule with the rank of law, as it follows from Article 53 EC to the extent that it entails the limitation of a right fundamental, and as constitutional jurisprudence has come to recognize (SSTC 292/2000 and 76/2019, among others), of the Court of Justice of the Union

European (STJUE 08.04.2014, Digital Rights Ireland, among others) and the European Court of Human Rights (STEDH 07.06.2012, Cetro Europa 7 and Di Stefano vs. Italy, among others). In this sense, article 8.2 of Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights (LOPDGDD) establishes that "The treatment of personal data can only be considered based on the fulfillment of a mission carried out in the public interest or in the exercise of public powers conferred on the person in charge, in the terms provided for in article 6.1 e) of Regulation (EU) 2016/679, when it derives from a competence attributed by a rule with the force of law. ". Article 9 LOPDGDD is pronounced in similar terms regarding the processing of data from special categories of data, such as health data.

The Decree-Law constitutes a norm with the rank of law, and if it affects a fundamental right, such as the right to the protection of personal data, the analyzed regulation does not involve the essential regulation or the direct development of the fundamental right (question already done by the RGPD and Organic Law 3/2018), so it would not go against Article 64 EAC. Therefore, as recognized in STC 139/2016, a Decree-Law is a suitable rule to enable a certain processing of personal data.

III

The first two sections of the proposal under report establish two different treatments. On the one hand, it is established that the Secretary of Public Health must have the Catalonia Vaccination Register in which the data relating to vaccination against Covid-19 and other disease vaccines must be incorporated immunopreventable; on the other hand, the mandatory communication of data to this register is established both by the centers and health services of the Integral Health System of Public Use of Catalonia (SISCAT) and other entities that provide health services on behalf of the Catalan Service of Health, as for the rest of the health centers and services.

The provision at legal level of both one and the other treatment can be authorized in articles 6.1.e) and 9.2.h) ii) of the RGPD. The creation of a register that includes the information available to the Department on vaccination matters is already part of the treatments that the Department can currently carry out given the public health powers granted to it by current legislation. However, the regulation of the register at a legal level provides the system with greater transparency and legal certainty, especially with regard to the determination of the information that this register must contain.

The second treatment that is foreseen, that is, the communication of the vaccination data available to the private centers, does constitute a new treatment, which the legal provision that is intended to be approved can carry out by virtue of the aforementioned articles 6.1. e) and 9.2.i) of the RGPD and which is clearly proportionate to the objective pursued, as can be seen from the supporting report that accompanies the proposal.

However, according to Recital 41 of the RGPD, "said legal basis or legislative measure must be clear and precise and its application foreseeable for its recipients, in accordance with the jurisprudence of the Court of Justice of the European Union (hereinafter, "Court of Justice") and the European Court of Human Rights." In this sense, for example, the SSTEDH of September 6, 1978 (Klas vs. Germany), August 2, 1984 (Malone vs. UK), July 30, 1998 (Valenzuela Contreras vs. Spain), 18 February 2003 (Prado Bugallo vs. Spain) or STC 76/2019.

In the case at hand, the subjects obliged to provide the information are defined, as is the subject that must receive it, and the information that must be included in the Register is also defined in detail. Thus, it must be registered in the said Register:

- Data relating to the identification of the recipients of the vaccines
- Data relating to its administration, including:
 - o Identification of the professionals who administer them
 - o Identification of the center where they are administered
 - o Data relating to the vaccination record (antigen, date of administration, batch, product supplied, manufacturing laboratory and national code of the product),
 - o Other data that establish the health authorities.
- In the case of the vaccine against Covid-19, the non-administration must be recorded including any of the following variables regarding the cause of its non-supply:

- o If it is due to the free decision of the recipient or his legal representative
- o If it is due to the existence of contraindications for its administration (indicating whether it is temporary or indefinite)
- o If it is to be in a situation of immunity.

However, the content of section 1 of the proposal raises some doubts both regarding the origin of the information that must be included in the Register, and regarding the reasons for non-supply.

Regarding the origin of the information, at first it may seem that the information would have its origin in the act of vaccination. Thus, in the centers that are part of SISCAT or that provide services on behalf of the Catalan Health Service, an integration would occur with the vaccination information contained in the shared clinical history (which may include not only vaccinations that occur in from this decree-law, but also those produced previously). In the case of other private centers, it seems that it would be based on the communication of the data collected by these centers when they carry out the vaccination (within five days or 24 hours depending on the type of vaccine), but it does not seem that the incorporation of information on previous vaccinations is foreseen in the Decree-Law.

Now, with regard to the vaccine against Covid-19, it is expected that with respect to people who have not been given the vaccine, information on the reason why it has not been given will also be included in the Register.

In the case of the SISCAT centers and centers that act on behalf of the SCS, it can be understood that this information will be collected at the time when these centers contact the people listed in the central register of insured persons or, perhaps, who have a medical history in the field of these entities and these people refuse the supply.

In the case of other private centers, however, it seems clear that these can collect the information of people who come to the center to be vaccinated, but on the other hand, it is not clear in the articulated text that these centers have the obligation to put - contact other people other than those who are interested in receiving the vaccine.

For this reason, it would be good to clearly define in the text, both the set of people from whom these specific data related to the vaccine against COVID-19 must be collected, and, where appropriate, whether private centers must collect information about people who have not expressed their intention to be vaccinated.

Secondly, with regard to the different options offered to justify the non-supply of the vaccine against COVID-19, it may be appropriate to expand the options offered in the proposal with a fourth option that could be called "others", because there may be other reasons other than those mentioned in the proposal. In any case, it should be a closed option without asking for other additional justifications, given that, otherwise, the request for the justification of non-administration could lead to the processing of special categories of data (for example if is for reasons of ideology, religion or beliefs) that could come into conflict with Article 16.2 CE.

This observation would also be extended to the first paragraph of section 3 of the proposal.

IV

Section 3 of the proposal still provides for a third, differentiated treatment. In this case, section 3 provides that the information originating in privately owned health centers and services that has been communicated to the "Catalan Vaccination Register" must be incorporated into the shared clinical history of Catalonia with consent expressed by the affected person. So, in this case the legal basis would be given by articles 6.1.a) and 9.2.a) of the RGPD

Regarding this issue, it must be said that to the extent that the information that private centers provide to the Registry is not provided in order for SISCAT to provide health care, it would be unnecessary to incorporate this information into the shared medical history. Remember in this sense that, in accordance with articles 9.1 and 11.1 of Law 21/2000, of 29 December, on the rights of information concerning the health and autonomy of the patient and the clinical documentation, the clinical history has a fundamentally assistance purpose. However, to the extent that it is envisaged that this information will only be included in the shared medical history if there is the express consent of the vaccinated person, it does not seem that this possibility should be excluded. In any case, it will be necessary to guarantee both the information to the affected persons and the free nature of the consent, that is to say that the vaccination is not conditional on this consent and that the fact of not consenting will not have negative consequences for the affected persons .

Conclusions

Having examined the proposed article to be included in a Decree-Law to create the Vaccination Register of Catalonia, it is considered adequate to the provisions established in the regulations on the protection of personal data, without prejudice to the considerations made in the legal basis III d this report.

Barcelona, November 30, 2020