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N/REF: 0059/2021

The consultation raises the adaptation to Regulation 2016/679 of the European Parliament and of the Council, of April 27, 2016, regarding the protection of natural persons with regard to data processing data and the free circulation of these data (RGPD) and the Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, (LOPDGDD), of the information requirement that carried out by the Spanish Medicines Agency (AEMPS, hereinafter) to the consultant (CTAEX) regarding the registration of movements of cannabis derived of its activity within the "Research and development project of Cannabis sativa L. genotypes to obtain extracts of cannabinoids" authorized by the AEMPS. This record may contain data of a personal nature and therefore must be carried out with the legal coverage enough.

CTAEX states that the AEMPS acts in the exercise of the powers attributed to it by Royal Decree 1275/2011, of September 16, which creates the State Agency "Spanish Agency for Medicines and Sanitary Products" and its Statute is approved, and in accordance with the established in the current LOPDGDD in its article 8, the norm that attributes the competence and that will allow the processing of data must be within the range legal and non-regulatory. So you question the request for personal data for lack of legal protection and, secondly, it raises whether said petition would be in accordance with the principle of data minimization contained in the article c) of the RGPD.

I

Regarding the processing of personal data carried out by the authorities, this

Legal Office has had the opportunity to pronounce itself on several occasions,

being the general criterion that would be applicable what is indicated in article 6.1

c), or e) of the RGPD according to what is included in the norm that is applicable to the

data controller. (Report 74/2019).

Article 6.1 of the RGPD provides the following:

The treatment will only be lawful if at least one of the

following conditions: (...)

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c) the treatment is necessary for the fulfillment of an obligation

law applicable to the data controller; (...)

e) the treatment is necessary for the fulfillment of a mission

carried out in the public interest or in the exercise of public powers

conferred on the data controller;

Recital 41 of the RGPD states that “When this Regulation

refers to a legal basis or a legislative measure, this does not require

necessarily a legislative act adopted by a parliament, without prejudice

of the requirements of conformity of the constitutional order of the State

member in question. However, such legal basis or legislative measure

must be clear and precise and its application predictable for its recipients,

in accordance with the case law of the Court of Justice of the European Union

(hereinafter "Court of Justice") and the European Court of Human Rights

Humans.

Recital 45 of the RGPD states that “When it is carried out in compliance

of a legal obligation applicable to the data controller, or if it is

necessary for the fulfillment of a mission carried out in the public interest or in

the exercise of public powers, the treatment must have a basis in the

Law of the Union or of the Member States.”

Now, the LOPDGDD establishes in its article 8 under the name

“Data processing due to legal obligation, public interest or exercise of

public powers” the following:

1. The processing of personal data can only be considered founded

in compliance with a legal obligation required of the controller, in

the terms provided in article 6.1.c) of the Regulation (EU)

2016/679, when so provided for by a rule of Union Law

European Union or a standard with the force of law, which may determine the

general conditions of the treatment and the types of data object of the treatment

same as well as the transfers that proceed as a result of the

compliance with the legal obligation. This rule may also

impose special conditions on treatment, such as adoption

of additional security measures or others established in the chapter

IV of Regulation (EU) 2016/679.

2. The processing of personal data can only be considered founded

in the fulfillment of a mission carried out in the public interest or in the

exercise of public powers conferred on the controller, in the terms

provided for in article 6.1 e) of Regulation (EU) 2016/679, when

derives from a competence attributed by a norm with the force of law.”

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That is to say, the Spanish legislator has determined that it should be a rule with rank of law, the instrument that either imposes an obligation on the person responsible of the treatment that entails the treatment of personal data, or that attributes to the person in charge of the treatment public competences that imply data treatment.

It is necessary to analyze the legal regime of licit drug trafficking and the powers that the AEMPS has in this regard.

II

In the first place, it is appropriate to cite Law 17/1967, of April 8, by which update the current regulations on narcotic drugs and adapt them to what is established in the 1961 United Nations Convention, which, despite the passage of time since its approval, it is still in force and is the first standard on which the action of the AEMPS must be based in the case object of study.

The joint analysis of several of its precepts proceeds to interpret it according to the current administrative organization, because obviously, in the year of its approval, neither the form of the State was the same as it is now, nor the Administrative organization.

It provides in its first Article, the following:

The Spanish State has the right to intervene, within its territory, cultivation and production, manufacture and extraction,

the

storage, transportation and distribution, import, export and

the transit of raw materials and narcotic products, as well as

its prescription, possession, use and consumption. Also, it corresponds to

Spanish State the right to prevent, prosecute and punish

facts that constitute an infraction or crime, provided for in this

legal regime

The fourth article provides the following:

In the General Directorate of Health, and within the services

pharmacists of the same, the Service of Control of

Narcotic drugs, with the tasks specified in article

following, and a Technical Commission, of an advisory nature, whose

composition and functions will be established by regulation.

As can be seen, a department of the Administration of the

State, the General Directorate of Health, (which with that name does not

does not exist at present and foreseeably not with the same

competencies) and the creation of a specific body is planned to carry out

carry out certain tasks, the Narcotics Control Service whose

functions that must be indicated in relation to the query object,

specified in the following precepts:

Fifth article.

The Narcotics Control Service will be responsible for:

a) The authorization, intervention, surveillance and control of cultivation, harvests,

storage, storage, production and manufacture of products or

Narcotic substances and their raw materials.

Seventh article.

The Narcotics Control Service may authorize crops of

plants intended for the production of narcotic substances or

can be used as such. But if the cultures are not brought to the

practice by authorized manufacturers, growers will come

obliged to deliver the harvest to the Service or to the manufacturers

authorized, who will take care of the treatment for its transformation.

Eighth article.

One. No natural or legal person may engage in the cultivation and

production indicated, not even for experimental purposes, without having

of the relevant authorization.

Two. The authorizations granted by the Control Service of

Narcotics will be specific to people, land, times,

specific plants and products, and will not entitle the availability of

plants or products. The Service will monitor the development of the cycles of

cultivation, including harvesting and its destination.

Article thirteen.

The Narcotics Control Service will be in charge of studying and

approval of the proposals for the acquisition of raw material or

produced from producing countries and domestic pricing

purchase and sale of processed raw material, and will exercise, in

any of the cases, a thorough inspection of the premises and

also of each and every one of the manufacturing phases and how many

people take part in it.

Article twenty.

One. The Narcotics Control Service, through records,

periodic parts and inspections, you will know at all times the

quantities that they have in stock and those that for the different purposes

are using the laboratories that prepare specialties, both from

human and veterinary medicine, the pharmaceutical warehouses of the

commercial network, pharmacies, medicine cabinets, sanatoriums,

hospitals and research and teaching care centers, and

will prevent the accumulation in them of narcotic substances in

quantities greater than those considered necessary for its normal

functioning.

In accordance with the foregoing, the regulations provide for a legal regime for

that it is derived that personal data processing may occur, to

consequence of the control and authorization work attributed to today

extinct Narcotics Control Service.

Therefore, it will be necessary to determine whether the AEMPS can currently

be considered the successor of said service and under what legal title.

III

The AEMPS in the requirements that it directed against the consultant protected her

performance in the provisions of article 7. 27 of Royal Decree 1275/2011, of

September 16, by which the State Agency "Spanish Agency for

Medicines and Health Products" and its Statute is approved, which

attributes “Develop state inspection functions and responsibilities

and control in the area of licit traffic and use of narcotic drugs and substances

psychotropic”,

However, the legal provision for the creation of the current AEMPS was

in the Fifth Additional Provision of Law 28/2006 of July 18, Agencies

state for the improvement of public services, which under the rubric

"Transformation of Public Bodies into State Agencies" was authorized

to the Government to proceed with said transformation, and to do so through

Royal Decree of the Council of Ministers at the initiative of the assigned Minister

of the respective Public Organism and at the joint proposal of the Ministers of

Economy and Treasury and Public Administrations.

That is to say, it was already foreseen in a norm with the rank of law -the aforementioned law of

agencies- the transformation and therefore the creation of the current AEMPS.

Taking into account said authorization by regulation with the force of law, you must

It should be noted that the current AEMPS replaces the autonomous body Agencia

Spanish Medicines and Health Products (OAAEMPS) and is subrogated and

it happens to him, among other aspects, in all his powers and functions.

This is indicated in the first additional provision of the aforementioned Royal Decree

1275/2011, of September 16, under the name "Suppression of the

autonomous body Spanish Agency of Medicines and Products

Toilets":

1. The autonomous body Agencia Española de

Medicines and Health Products. 2. From the entry into force

of this royal decree, the State Agency that is created will be

subrogated in all assets, rights and obligations of the

autonomous body abolished and will succeed it in all its powers

and functions.

3. The mentions that the current regulations make to the autonomous body

Spanish Agency for Medicines and Health Products,

they shall be understood as made to the new State Agency that is created.

That said, the legal regime of the OAAEMPS should be analyzed to

determine the attribution of powers related to lawful traffic control

of narcotics.

It is appropriate to go in the first place to Law 66/1997, of December 30, of

Fiscal, Administrative and Social Order Measures, which in its articles 89 and

90 provides the following:

Article 89. Creation of the Spanish Medicines Agency.

One. It is created, under the name of the Spanish Agency for

Medicinal product, a public body with the character of a

autonomous, in accordance with the provisions of articles 41 and 43 of the Law

6/1997, of April 14, on the Organization and Functioning of the

General State Administration, with legal-public personality

differentiated and full capacity to act, which will be governed by the provisions

in this Law and other applicable provisions.

Two. The Spanish Medicines Agency is attached to the Ministry

of Health and Consumption, which corresponds to its strategic direction, the evaluation and control of the results of its activity, through the Undersecretary of the Department.

Three. To the Spanish Medicines Agency, within the sphere of its competences, it has the precise administrative powers for the fulfillment of its purposes, in the terms foreseen by its statutes, in accordance with the applicable legislation.

(…)

Article 90. Functions of the Spanish Medicines Agency.

The functions of the Spanish Medicines Agency are: (...)

i) The competences related to narcotics and psychotropics that regulations are determined.

j) Any others that are attributed by legal regulations or regulations.

Taking into account the foregoing, it is expressly established by mandate law, the exercise of powers related to narcotics and psychotropics and makes a reference to the regulatory development.

Well, Royal Decree 520/1999, of March 26, approving the Statute of the Spanish Medicines Agency, for the purposes of this report the so-called OAAEMPS, establishes in its article 5.15 in relation to its functions the following:

The functions of the Spanish Medicines Agency are:

15. Develop state functions and responsibilities in matters of

trafficking and legal use of narcotic drugs and psychotropic substances.

In the same way, the current Royal Decree 1275/2011, of September 16, by the

the creation of the State Agency "Spanish Agency for Medicines and

Sanitary Products" and its Statute is approved, in its article 7.27 before

quoted, does the same.

IV

Another aspect that must be highlighted and related to the succession of

organs of the State Administration is that the aforementioned Law 17/1967, of 8

April, which updates the current regulations on narcotics,

attributed to the General Directorate of Pharmacy (DGF) through the Service of

Control of Narcotic Drugs the powers that are being subject to

analysis in this report.

Well, it should be noted that the aforementioned DGF with the successive changes of

government from that date and therefore, of structuring the

ministerial departments, their functions were assumed by the also today

extinct General Directorate of Pharmacy and Health Products, and whose mention

expressed in Law 66/1997, of December 30 and in Royal Decree 520/1999,

of March 26, must be indicated for the purposes of completing the succession of

competencies that have been revealed in this report in favor of

the current AEMPS.

In effect, Article 97 provides. Succession and effective constitution of the Agency

Spanish of Medicine of the aforementioned Law 66/1997, of December 30

in section One, the following:

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The Spanish Medicines Agency will succeed the General Directorate
Pharmacy and Medical Devices and the National Center for
Pharmacobiology in the exercise of all functions
mentioned in article 90 of this Law that have been
carried out by those, which will be subrogated in the totality of
the goods, rights and obligations affected or constituted by virtue of
the aforementioned functions.

And section two of the first additional provision of the
Royal Decree 520/1999, of March 26, indicating that:

2. The Spanish Medicines Agency will take charge of the functions
referred to in article 5 of its Statute and will succeed the same
General Directorate of Pharmacy and Health Products, to the National Center
of Pharmacobiology of the Carlos III Health Institute and the Directorate
General of Livestock,

That is to say, the competence attribution that Law 17/1967, of April 8, made to
favor of the former DGF, must be interpreted as made to the General Directorate of
Pharmacy and Sanitary Products, and by substitution to the OAAEMPS and finally to
the current AEMPS. All this without prejudice to the express attribution
competence that Law 66/1997 of December 30 makes in favor of the
OAAEMPS in the field of drug control.

Taking into account the above, it can be affirmed that the competition for the
control over legal drug trafficking has been attributed by

norm with legal rank, both Law 17/1967, of April 8, by which

update the current regulations on narcotics, such as the Law

66/1997, of December 30, (both in force) to a body of the structure

administration of the State, which after the successive modifications of its statute

legal, is the current AEMPS and which exercises these functions through the Area of

Narcotic and Psychotropic Drugs of the Department of Inspection and Control of

Medicines.

Said interpretation cannot fail to be shared by the consultant, among

other aspects, because the authorization and extension granted in its favor by the

AEMPS, in relation to the "Research and development project of genotypes

of Cannabis sativa L. to obtain cannabinoid extracts", was

submits to the aforementioned Law 17/1967, of April 8, that is, a law where there is no

expressly the mention of the current AEMPS and in this regard, there is no evidence that

raise doubts about what has just been indicated, that the indications made

in said norm in favor of the State, the DGF, or the Control Service of

Narcotic drugs, must now be understood by the AEMPS.

Therefore, the request for information made by the AEMPS in the

exercise of its inspection function, and therefore the processing of data that

carries rigged, it would be protected by article 6.1 e) of the RGPD in

relation to article 8.2 of the LOPDGDD.

v

In relation to the second question that arises, it refers to whether the data requested by the AEMPS referring to the identification of the recipients that recorded in the accounting record, complies with the principle of minimization.

The consultant raises the adaptation to said principle of the request generic of the relationship of all customers from January 1, 2020, with independence of THC content, and how it should be provided, taking into account that CTAEX first communicated moment in an anonymized way, that is, adding an identifier and that the AEMPS reiterated its request requesting the complete identification of each client. Given what CTAEX for its implications related to the data protection did not comply with it.

As a starting point, it should be noted that both the RGPD and the LOPDGDD apply to the processing of data of natural persons (article 1.1 RGPD) and with respect to legal persons, it applies to the persons who represent them,

Thus, in Report 4/2021, it was indicated that "they are excluded from the application of the regulations on personal data legal persons, but its scope protector extends to the natural persons who represent them, whose data personal data must be treated subject to the provisions of the RGPD and the LOPDGDD".

Therefore, if in the case analyzed when the AEMPS requests the identification of clients that appear in the register of "accounting samples laboratory external services" we are not dealing with natural persons would not be applicable data protection regulations and therefore could not wield or oppose any exception by CTAEX related to a possible breach of the RGPD or LOPDGDD.

In other words, CTAEX could not deny the identification of customers with the

pretext of not wanting to breach the data protection standard, since it would not be

of application.

That said, the analysis of the principles of limitation of the purpose and

minimization of data provided for in article 5.1 b) and c) of the RGPD.

Article 5.1 of the RGPD provides that personal data will be,

b) collected for specific, explicit and legitimate purposes, and will not be

subsequently processed in an unshareable manner for said purposes (...)

("Purpose Limitation")

c) adequate, pertinent and limited to what is necessary in relation to the

purposes for which they are processed ("data minimization");

Taking into account the foregoing, for data processing to be in accordance

to the RGPD and the LOPDGDD, it is not enough to comply with the principle of

legality, discussed above, but must also observe the

principles of purpose limitation and minimization.

In relation to the number of individuals who could be affected

by the request, it must be remembered here that the jurisprudence of the

Constitutional Court is against the massive communication of data to the

Public Administrations, as stated in its judgment 17/2013, of

January 31, 2013, in which it interprets article 16.3 of the Law of Bases of

Local Regime, related to the communication of data from the municipal register, and

whose conclusions are fully applicable to the present case.

As it has been interpreted by the TC in said judgment (FJ 8), this

precept refers to the non-consensual transfer of data related to the

residence or domicile to other public administrations that so request

only in those cases in which, for the exercise of its powers,

be those relevant data. In short, this petition, which does not refer

specifically to the transfer of data from the register with regard to the data

of foreigners, its purpose is to be able to dispose of the data related to the

residence or domicile that appear in the municipal register, (...).

way, in accordance with the Organic Law on data protection, the purpose

that justified the collection of data by an Administration

does not prevent the subsequent destination of the data for its use in purposes

different from those that motivated its collection, respecting, in any case, the

principle of reserve of law to establish said change, (...) the Law of bases

of local regime in its condition, in addition, of regulatory norm of a file

how the municipal register can foresee transfers of data between

Public administrations.

(...) the data transferred must be strictly necessary for the

fulfillment of the functions assigned to the administrative bodies

in such a way that the request for those data that result

relevant, since it is necessary to distinguish between the analysis and monitoring of a

individualized situation relating to a specific case and the supply

generalized and indiscriminate of all the information contained in a record

personal. The precept has contemplated both extremes in such a way that

any transfer of data from the register must be based on the need

by the assignee Administration acting in the exercise of its

competences, to know, in each specific case, the data related to the domicile of the affected person, extremes that must be adequately assessed by the assignor in order to assess whether the data requested is really necessary, pertinent and proportionate, taking into account the competence that intends to exercise the assignee Administration (art. 4 in fine of Law 30/1992).

It is thus a rule in itself restricted to data relating to the residence and domicile in each specific case, and to which they will result from application, needless to say, the rest of the principles and provisions that make up the content of the right recognized in the legislation on Data Protection.

Likewise, regarding the principle of proportionality, the Judgment of the Court Constitutional 14/2003, of January 28, recalls the following:

“In other words, in accordance with a settled doctrine of this Court, the constitutionality of any restrictive measure of rights fundamental principles is determined by the strict observance of the principle of proportionality. For the purposes that matter here, it suffices to remember that, for check if a restrictive measure of a fundamental right passes the judgment of proportionality, it is necessary to verify whether it meets the three requirements or following conditions: if the measure is likely to achieve the objective proposed (judgment of suitability); if, in addition, it is necessary, in the sense that There is no other more moderate measure to achieve this purpose with equal efficacy (judgment of necessity); and, finally, if it is weighted or

balanced, because it derives more benefits or advantages for the interest

general than damages on other goods or values in conflict (judgment of

proportionality in the strict sense; SSTC 66/1995, of May 8 [RTC

1995, 66], F. 5; 55/1996, of March 28 [RTC 1996, 55], FF. 7, 8 and 9;

270/1996, of December 16 [RTC 1996, 270], F. 4.e; 37/1998, of 17

February [RTC 1998, 37], F. 8; 186/2000, of July 10 [RTC 2000, 186], F.

6)."

From what was transcribed above, and from the rest of the legal foundation

contained in STC 17/2013, and from the principle of proportionality, it turns out that the

TC has determined that (i) indiscriminate and massive access to

to personal data (ii) the data in question requested must be relevant

and necessary (iii) for the purpose established in the precept (iv) the request for

access to specific personal data must be motivated and justified

expressly, (v) in such a way that it enables its control by the assignor (vi) and

a tortuous use of that ability with massive accesses is avoided. This supposes (vii)

that the possibility of analyzing whether in each case

In particular, access was protected by the provisions of the law.

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In the present case, and without prejudice to the fact that the terms

of the inspection and control actions being carried out by the

AEMPS in relation to the consultant and whose relevance corresponds to the trial

of the same, from the perspective of the right to data protection,

the request object of analysis, provided that it affects data of a

staff, you should meet the requirements that have just been indicated to be

respectful of the principle of minimization and limitation of the purpose, in

relation to the powers that the current legal system attributes to the

AEMPS related to legal drug trafficking, with which the relevance and

The need for treatment must be adequately and expressly justified.

by the data requester.