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Injunction order against Artemisia s.p.a. - May 13, 2021

Record of measures

n. 193 of May 13, 2021

THE GUARANTOR FOR THE PROTECTION OF PERSONAL DATA

IN today's meeting, which was attended by prof. Pasquale Stanzione, president, Professor Ginevra Cerrina Feroni, vice president, dr. Agostino Ghiglia and the lawyer Guido Scorza, members and the cons. Fabio Mattei, general secretary;

GIVEN the Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, concerning the protection of individuals with regard to the processing of personal data, as well as the free circulation of such data and which repeals Directive 95/46 / EC, "General Data Protection Regulation" (hereinafter the "Regulation");

GIVEN the legislative decree 30 June 2003, n. 196 containing the "Code regarding the protection of personal data, containing provisions for the adaptation of the national system to Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, relating to the protection of individuals with regard to the processing of personal data, as well as to the free circulation of such data and which repeals Directive 95/46 / EC (hereinafter the "Code");

GIVEN the Regulation n. 1/2019 concerning internal procedures with external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor for the protection of personal data, approved by resolution no. 98 of 4/4/2019, published in the Official Gazette n. 106 of 8/5/2019 and in www.gpdp.it, doc. web n. 9107633 (hereinafter "Regulation of the Guarantor no. 1/2019");

Having seen the documentation in the deeds;

Given the observations made by the secretary general pursuant to art. 15 of the Guarantor Regulation n. 1/2000 on the organization and operation of the office of the Guarantor for the protection of personal data, in www.gpdp.it, doc. web n. 1098801;

Speaker prof. Pasquale Stanzione;

WHEREAS

1. The complaint

In the twentieth century a complaint was made against the company Artemisia s.p.a. (hereinafter "Company") concerning the

methods of acquiring the consent of the interested parties for sending the online report. In particular, it was highlighted, with suitable documentation, that the complainant had been asked for a single consent to the processing of personal data, both for the activation of the online reporting procedure, and for being included in the "ALTAMEDICA Newsletter" aimed at providing information on the services provided by the structure.

2. The preliminary activity

The Authority has formulated a request for information, with a note of the XX (prot.n.XX), aimed at knowing, in particular, the specific and distinct purposes pursued through the processing of data on the health of the interested parties, the relative legal bases, and any useful element in order to comply with the obligation to acquire autonomous consents for the pursuit of distinct purposes. On the same occasion it was pointed out that, at the time of the assessment, the Authority had not received the communication by the Company of the contact details of the Personal Data Protection Officer (hereinafter, "DPO"), required by 'art. 37, par. 7 of the Regulation.

With a note dated XX, the Company provided feedback, declaring that:

- In relation to the distinct purposes pursued through the processing of data on the health of the interested parties, "the same will be processed, as indicated in the privacy policy, for the following purposes: clinical and laboratory analyzes, ultrasonic diagnostics, prenatal diagnosis, specialist visits, molecular biology, cytogenetics, outpatient surgery, diagnosis and therapy of couple infertility, cardiology and all the branches related to the multi-specialist outpatient clinic ";
- in relation to "the obligation to acquire autonomous consents for the pursuit of distinct purposes (in the case that here we are concerned with online reporting and sending newsletters or other promotional material), it should be noted that this was a mere error pagination computer scientist. More specifically, the authorization / non-authorization boxes that had been set up in order to collect consent only for promotional material have been erroneously deleted ";
- "in any case, a consent has been formalized for the authorization of online reporting, and a different and explicit consent for the authorization to receive the newsletter; obviously the explicit consent, already in place previously, remains in place for the authorization to process personal data for the part relating to health services ";
- the contact details of the DPO, Dr. Gian Luca Bucciarelli ".

A new model of "Information provided pursuant to art. 13-14 of the GDPR "in which, in the part relating to the" Withdrawal of On-line Reports - sending results by email and consultation via the Internet site ", the reference to the authorization to enter the

data of the interested parties in the Altamedica Newsletter was removed to receive information on the services provided by the structure.

With reference to what emerged, from the examination of the documentation examined, taking into account that the described conduct did not comply with the relevant legislation on the protection of personal data, the Office, with deed of XX, prot. n. XX, notified the Company, pursuant to art. 166, paragraph 5, of the Code, the initiation of the procedure for the adoption of the measures referred to in art. 58, par. 2, of the Regulations, inviting her to produce defensive writings or documents to the Guarantor or to ask to be heard by the Authority (art.166, paragraphs 6 and 7, of the Code, as well as art.18, paragraph 1, l. N.689 of 24 November 1981)

In particular, the Office, in the aforementioned deed, found that the Company:

- has not provided the interested parties, as part of the information prepared, some of the elements required by art. 13 of the Regulation (the contact details of the Data Protection Officer, the legal basis of the processing, the retention period of personal data); this, in violation of the aforementioned art. 13 of the Regulations;
- has carried out a processing of health data, by sending "newsletters containing information on the services provided by the structure", in the absence of the legal requirements provided for by art. 9 of the Regulation, considering that the consent acquired for the processing of data in the context of online reporting does not constitute a prerequisite for the processing for the purpose of sending newsletters. This, as the consent would not be given in relation to the specific "promotional" purpose and, in any case, it would not be "freely provided", considering in particular the prejudice that the interested party would have suffered in case of refusal (the impossibility of accessing the online reporting); this, therefore, in violation of the basic principles of processing pursuant to art. 5 and 9 of the Regulations;
- has not published, being required, the contact details of the Data Protection Officer and has not communicated them to the Guarantor; this in violation of art. 37 of the Regulation.

With a note dated the XXth, the Company sent its defense briefs, in which, in particular, it was represented that:

- a) "with regard to the legal basis of the processing, the latter is lawful by virtue of art. 6 paragraph a) of the Regulations. And in fact, the interested party (in our case the patient) gives consent to the processing of their personal data for one or more specific purposes that are slavishly listed in our privacy model and which are reported below: clinical and laboratory analyzes, diagnostics ultrasound, prenatal diagnosis, specialist visits, molecular biology, cytogenetics, outpatient surgery, diagnosis and

therapy of couple infertility, cardiology and all branches related to the multi-specialist outpatient clinic ";

b) "with regard to the retention period of the data, these are processed for the period of time strictly necessary for the performance of the requested service and are kept for 10 years, in order to cover the statutory limitation period. In fact, any claims for compensation can be made within 10 years of the occurrence of the event against which the patient can make claims ";

c) "with reference to the processing of data for sending newsletters containing information on the services provided by the structure, in the absence of the legal conditions provided for by art. 9 of the Regulations, it is reiterated that this correction had already been made following the previous letter received. And in fact, in the privacy model already delivered to the S.V., there is no longer any mention of sending any newsletters ".

With the same note he also communicated some contact details of the Data Protection Officer: (dr. Gian Luca Bucciarelli - e-mail address: studioprof.bucciarelli@gmail.com).

On the XXth, the hearing was held, requested by the data controller, during which, in relation to the reported violations, what had already been declared and, in any case, specified that:

- "the requested elements were immediately supplied and the necessary corrections were made; it is asked to take into consideration the promptness with which it acted, correcting the disputed ";
- "with regard to the information, the data of the DPO with the relevant contact details have been entered";
- "in relation to the sending of newsletters, it is clear that the acquisition of a single consent for online reporting and for sending newsletters is due to a mere error in the formal layout, which was immediately eliminated, completely removing the part relating to the newsletter from the information ".

3. Outcome of the preliminary investigation

Given that, unless the fact constitutes a more serious crime, whoever, in a proceeding before the Guarantor, falsely declares or certifies news or circumstances or produces false documents or documents, is liable pursuant to art. 168 of the Code ("False declarations to the Guarantor and interruption of the execution of the tasks or the exercise of the powers of the Guarantor"), upon the outcome of the declarations made to the Authority during the procedure as well as the examination of the documentation acquired, that the Company has processed personal data in violation:

- of art. 13 of the Regulation, since, at the time the complaint underlying this provision was proposed, the information provided

did not contain a series of elements provided for by the same Regulation and essential for achieving the objective of transparency underlying the fulfillment, including which: the contact details of the data controller and the Data Protection Officer, the retention period of the same and the legal basis of the treatments;

- the basic principles of the processing referred to in Articles 5 and 9 of the Regulations for having processed health data by sending "newsletters containing information on the services provided by the structure", on the basis of a non-specific consent as expressly required by art. 9, par. 2, lett. a) of the Regulations, as acquired jointly with that for the processing of data as part of the online reporting activity. Furthermore, the aforementioned consent cannot be considered "freely given", considering that the interested party, if he had legitimately believed to refuse it, would inevitably have suffered a prejudice, consisting in the impossibility of accessing the online reporting (see Recital no. 32, 42 and 43 and point 3. Provision no. 36 of November 19, 2009, containing "Guidelines on the subject of on-line reports", in www.gdpd.it, web doc. no. 1679033, deemed compatible with the aforementioned Regulation and with the provisions of decree no. 101/2018; see Article 22, paragraph 4, of the aforementioned legislative decree no. 101/201);

- of art. 37, par. 1 and 7 of the Regulation, in relation to the obligations concerning the DPO, which certainly affect the Company, considering that its main activity consists in the large-scale processing of particular categories of personal data referred to in art. 9 of the Regulation (see art. 37, par. 1, lett. C) and point 3 of the provision. n. 55 of 7 March 2019, doc. web n. 9091942, relating to the clarifications provided by the Guarantor on the application of the rules for the processing of data relating to health in the health sector). In fact, the same Company, constituting one of the largest prenatal diagnosis centers in Italy, offers diagnostic services to thousands of patients, in particular, pregnant patients (for a total of about 100,000 annual admissions) and has an innovative genetics laboratory. for the complete study of DNA and genetic errors in the various aspects of prenatal diagnosis, pediatrics, pharmacogenomics, nutrigenomics, oncology (see website www.altamedica.it).

Regardless of the date of designation of the DPO, an internal verification has ascertained that the planned communication of the DPO's contact details to the Authority had not yet been carried out at the time the complaint was lodged. In this regard, moreover, although the Company declared, with a note of the XXth, that it "proceeded to communicate to the S.V., through the appropriate procedure prepared for this purpose, the contact details of the DPO, Dr. Gian Luca Bucciarelli ", from the research carried out at the Guarantor's Protocol Office (minutes in deeds), there has been no communication to the Authority to date - pursuant to art. 37, par. 7, of the Regulation - of the contact details of the DPO. In particular, it appears in documents that, on

the XXth date, the online form was filled out, without however completing the process, due to an erroneous indication of the address to which to receive the instructions for the conclusion of the procedure.

Moreover, from a research carried out by the Authority, on the date of the adoption of this provision, two information notices were published on the Company's website, as part of the activity of "Withdrawal of ALTAMEDICA reports" and "Privacy and Cookie Policy" in which the contact details of the DPO are not indicated. Furthermore, in the model of "Information provided pursuant to art. 13-14 of the GDPR ", in http://www.altamedica.it/ALTAMEDICA_Modulo_Privacy_GDPR.pdf, you can still find the single wording bearing " I also authorize to leave the report available ONLINE, beyond the 45 days provided for by the Guide on the subject of on-line reports - November 19, 2009 (Official Gazette No. 288 of December 11, 2009) and I authorize to insert myself in the ALTAMEDICA newsletter to receive information on the services provided by the structure ".

4. Conclusions

The elements reported by the owner in the defense briefs and in the hearing are insufficient to overcome the objections raised by the Office with the act of initiation of the procedure and, therefore, to allow the filing of the procedure, not recurring, however, any of the cases provided for by art. 11 of the Guarantor Regulation n. 1/2019.

In fact, the concise deductions of the owner invoked provisions not conferring the treatments in question and, in other cases, limited themselves to providing some elements of which the lack of indication in the information provided pursuant to art. 13 and 14 of the Regulation (for example, with reference to the data retention period) without, however, providing justification for the aforementioned omission. The information referred to in Articles 13 and 14 of the Regulations must in fact be provided before the start of the processing itself to the interested party and not to the Authority in the event of (possible) control.

Furthermore, in relation to the processing of data for the purpose of sending newsletters, it was reported that the "Information provided pursuant to art. 13-14 of the GDPR ", removing the reference to the authorization for the data of interested parties in the Altamedica Newsletter to receive information on the services provided by the structure. This circumstance was documented by attaching a new model to the aforementioned note from the XXth Company; from a check carried out by the Office, the model prior to the aforementioned modification is still published on the Company's website (see http://www.altamedica.it/ALTAMEDICA_Modulo_Privacy_GDPR.pdf). With regard to the conduct, the company justified the acquisition of a single consent by referring to "a mere IT error in the layout", deriving from an erroneous cancellation of the "authorization / non-authorization boxes that had been prepared in order to collect the consent for promotional material only ".

This assertion has not been proven and is not very credible considering that, in the model, the authorization formulas are linked by a conjunction and are included in the same sentence, circumstances that confirm the belief that the violation was intentional.

Therefore, the preliminary assessments of the Office are confirmed and the unlawfulness of the processing of personal data carried out by the Company is noted, in violation of Articles 5, 9, 13 and 37 of the Regulations, within the terms set out in the motivation.

In this context it is considered necessary, due to the failure to implement the obligations required by the Regulation, to order, pursuant to art. 58, par. 2, lett. d), of the Regulation, to Artemisia s.p.a. to provide:

- the integration of the information provided pursuant to art. 13 of the Regulation with the missing elements relating to the contact details of the data controller and the Data Protection Officer, the retention period of the same and the legal basis of the treatments;
- to the modification of the model of "Information provided pursuant to art. 13-14 of the GDPR ", which can be found at http://www.altamedica.it/ALTAMEDICA_Modulo_Privacy_GDPR.pdf, by removing the reference to the authorization to enter the data of the interested parties in the Altamedica Newsletter to receive information on the services provided by the structure;
- to the communication to this Authority (by following the specific procedure available on the Guarantor's website at <https://servizi.gpdp.it/comunicazionerpd/s/>) of the contact details of the Data Protection Officer designated by the Company , as well as to arrange for the corresponding publication on the institutional website, pursuant to art. 37, par. 7, of the Regulation.

5. Adoption of the injunction order for the application of the pecuniary administrative sanction and ancillary sanctions (articles 58, par. 2, lett. l and 83 of the Regulation; art. 166, paragraph 7, of the Code).

The violation of articles 5, 9, 13 and 37 of the Regulations, determined by the processing of personal data, the subject of this provision, carried out by the Company, is subject to the application of a pecuniary administrative sanction pursuant to art. 83, par. 4, lett. a) and par. 5, lett. a) of the Regulations.

Consider that the Guarantor, pursuant to art. 58, par. 2, lett. i) and 83 of the Regulations, as well as art. 166 of the Code, has the power to "inflict an administrative pecuniary sanction pursuant to Article 83, in addition to the [other] [corrective] measures referred to in this paragraph, or instead of such measures, depending on the circumstances of each individual case "and, in

this context," the College [of the Guarantor] adopts the injunction order, with which it also disposes with regard to the application of the ancillary administrative sanction of its publication, in whole or in excerpt, on the website of the Guarantor pursuant to Article 166, paragraph 7, of the Code "(Article 16, paragraph 1, of the Guarantor Regulation no. 1/2019).

The aforementioned administrative fine imposed, depending on the circumstances of each individual case, must be determined in the amount taking into account the principles of effectiveness, proportionality and dissuasiveness, indicated in art. 83, par. 1, of the Regulation, in light of the elements provided for in art. 83, par. 2, of the Regulation in relation to which, in particular, although there are no previous violations, it is noted that:

- the processing of data carried out for the purpose of sending newsletters by the Company concerns data on the health of a large number of patients, potentially all those who have joined the online reporting service (Article 83, paragraph 2, letter a), e) and g) of the Regulations);
- the violations have, at least with reference to consent, intentional character and lasted for a long period of time (with reference, at least to the communication of the contact details of the DPO to the Authority, and to the information provided pursuant to art. 13 of the Regulation, the violations date back to at least 25 May 2018, the date of application of the Regulation) (Article 83, paragraph 2, letter a) and b) of the Regulation);
- the lack of cooperation shown by the Company is evident in the fact that it has not yet remedied the violations, so much so that the aforementioned model of "Information provided pursuant to arts. 13-14 of the GDPR ", on the Company's website and the communication to this Authority has not yet been made (following the specific procedure available on the Guarantor's website at <https://servizi.gdpd.it/comunicazionerpd/s/>) the contact details of the DPO (Article 83, paragraph 2, letter f) of the Regulation).

On the basis of the aforementioned elements, considered as a whole, together with the assessment of the economic conditions of the Company, it is believed to determine the amount of the pecuniary sanction provided for by art. 83, par. 5, lett. a) of the Regulations, to the extent of € 100,000 (one hundred thousand) for the violation of Articles 5, 9, 13, 37 of the Regulation as a pecuniary administrative sanction, pursuant to art. 83, par. 1, of the Regulation, effective, proportionate and dissuasive.

It is also believed that the ancillary sanction of the publication on the website of the Guarantor of this provision, provided for by art. 166, paragraph 7, of the Code and art. 16 of the Guarantor Regulation n. 1/2019, in relation to the particular category of

personal data processed and the potential number of data subjects.

Finally, it is noted that the conditions set out in art. 17 of Regulation no. 1/2019 concerning internal procedures with external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor.

WHEREAS, THE GUARANTOR

declares the unlawfulness of the processing of personal data carried out by Artemisia s.p.a for the violation of articles 5, 9, 13, 37 of the Regulations in the terms set out in the motivation;

ORDER

pursuant to art. 58, par. 2, lett. i) and 83 of the Regulations as well as art. 166 of the Code, to Artemisia s.p.a., with registered office in Rome, Viale Liegi, n. 41, VAT number 00929551000 to pay the sum of Euro 100,000.00 (one hundred thousand), as a pecuniary administrative sanction for the violations indicated in the motivation; it is represented that the offender, pursuant to art. 166, paragraph 8, of the Code, has the right to settle the dispute by paying, within thirty days, an amount equal to half of the sanction imposed;

INJUNCES

pursuant to art. 58, par. 2, lett. d), of the Regulations, to Artemisia s.p.a., in the person of the pro-tempore legal representative, to provide:

- the integration of the information provided pursuant to art. 13 of the Regulation with the missing elements relating to the contact details of the data controller and the Data Protection Officer, the retention period of the same and the legal basis of the treatments;
- to the modification of the model of "Information provided pursuant to art. 13-14 of the GDPR ", which can be found at http://www.altamedica.it/ALTAMEDICA_Modulo_Privacy_GDPR.pdf, by removing the reference to the authorization to enter the data of the interested parties in the Altamedica Newsletter to receive information on the services provided by the structure;
- to the communication to this Authority (by following the specific procedure available on the Guarantor's website at <https://servizi.gdpd.it/comunicazionerpd/s/>) of the contact details of the Data Protection Officer designated by the Company , as well as to arrange for the corresponding publication on the institutional website, pursuant to art. 37, par. 7, of the Regulation;

HAS

- pursuant to art. 166, paragraph 7, of the Code and by art. 16, paragraph 1, of the Guarantor Regulation n. 1/2019, the publication of this provision on the website of the Guarantor;

- the annotation of this provision in the internal register of the Authority, provided for by art. 57, par. 1, lett. u), of the Regulations, violations and measures adopted in compliance with art. 58, par. 2, of the Regulation.

Pursuant to art. 157 of the Code, also requests Artemsia S.p.A. to communicate which initiatives have been undertaken in order to implement the provisions of the previous point no. 1 of this provision within thirty days of its notification;

Pursuant to art. 78 of the Regulation, of art. 152 of the Code and 10 of Legislative Decree no. 150/2011, against this provision, it is possible to appeal before the ordinary judicial authority, under penalty of inadmissibility, within thirty days from the date of communication of the provision itself or within sixty days if the applicant resides abroad.

Rome, May 13, 2021

PRESIDENT

Stanzione

THE RAPPORTEUR

Stanzione

THE SECRETARY GENERAL

Mattei