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Injunction order - April 15, 2021

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n. 144 of 15 April 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 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](http://www.gpdp.it), doc. web n. 9107633 (hereinafter "Regulation of the Guarantor no. 1/2019");

GIVEN the documentation in the deeds;

HAVING REGARD to the observations made by the Secretary General pursuant to art. 15 of the Guarantor Regulation n. 1/2000 on the organization and functioning of the office of the Guarantor for the protection of personal data, Doc. web n. 1098801;

Speaker Dr. Agostino Ghiglia;

## WHEREAS

1. The violation of personal data and the investigation activity

The local social health unit no. 9 Scaligera (hereinafter the Company) sent the Authority a communication of personal data breach, pursuant to art. 33 of the Regulation, regarding the dissemination of data on the health of a patient, by means of the projection, by Dr. XX (in service at the Company), in a medical conference of some slides relating to a clinical case addressed by the same and the subsequent publication of the same on the website of the Triveneta Society of Surgery (hereinafter the Society). On this occasion, the aforementioned clinical case was awarded by the aforementioned Company as the "Best clinical case 2017".

According to what was communicated, following the legal action taken by the aforementioned patient, the Company took an active part in order to remove the aforementioned slides from the Company's website, also intervening on the "possibility of tracing the images through the search engine" .

From the documentation on file it emerges that, in the aforementioned slides, are reported: the initials of the patient, age, sex, detailed anamnesis of the pathology suffered by the same, details on the hospitalizations carried out from 1980 to 2016 and on the surgical interventions undergone in this period, indicating the dates of hospitalization and surgery (in many cases the day, month and year of the same is reported), the surgery unit that performed the operations, the days of hospitalization, numerous diagnostic images (14), as well as 22 photographs portraying the person concerned during surgery.

According to the opinion of the patient's legal representative in the formal notice, the aforementioned information "does not guarantee the impossibility of identifying in the person (of his client) (...) the person who has undergone the intervention".

In support of the warning given by the lawyer of the aforementioned patient, printouts of the results made on the "Google" search engine were produced following the query of the same with the indication of the particular type of intervention carried out and of the diagnosis (ileal laparostomy; leiomyosarcoma paravesicale), from which it was possible to trace the web addresses where the aforementioned slides were published.

From the documentation on file it also emerges that Dr. XX, for the purpose of preparing the aforementioned slides, used the data and health documents present in the computer archives of the Company, as well as photographic material created by the same as part of the treatment path of the 'concerned by the same carried out within the aforementioned Company.

As part of the investigation, initiated by the Office regarding the aforementioned communication of violation, information was acquired from the aforementioned Company, from Dr. XX and from the aforementioned Company.

From the elements and documentation in deeds, also acquired following the aforementioned requests for information, it

emerged that the Healthcare Company has not received an authorization request from Dr. XX, nor has it issued any authorization for the use of the logo. company on the occasion of the presentation of the aforementioned slides for the purposes of participation in the competition relating to the "Best clinical case 2017".

From the documentation on file it is also clear that Dr. XX has filled in the registration form for the aforementioned prize of the Triveneta Society of Surgery, declaring the paternity of the work presented for the purposes of participation in the competition. In particular, the Office requested information from Dr. XX (note of January 22, 2019) who provided feedback with a note of February 2, 2020 in which she represented, in particular, that:

"The patient had to give his consent to the treatment for treatment purposes, for the constitution and feeding of the health dossier, for the inclusion in the dossier of previous data. In the relative Information on data processing, the Company informed the patient that the processing took place for the pursuit of the purpose of "epidemiological investigation and scientific research";

"During the acquisition of the photographs, the patient was informed of the purpose and collaborative, as the members of the staff involved in the clinical activity during the dressings can testify";

"Subsequently the opportunity arose to examine the clinical case at the congress for the purpose of scientific sharing and also, given the complexity of the case itself, in order to obtain further useful insights on the treatment in progress in the direct interest of the patient. The identity was concealed with the use of the initial, as was the practice during the presentation of clinical cases. The remaining elements (anamnesis, sex, age and timing) constitute the usual information suitable and necessary for the fruitful discussion of the clinical case among the scientific community. In any case, they do not allow to trace the subject, guaranteeing its non-identifiability. The lack of such elements in the discussion of the case would render the work useless ";

"No one imagined a publication could take place on the website of the Triveneta Society of Surgery";

"The authorization to use the logo was not requested since it is a clinical case of particular scientific interest and related to the company's activity, in accordance with the convention practice in the medical-scientific field. There appears to be no regulation at the time ".

In relation to the results of the aforementioned investigation, the Office, with deed no. 22808 of 22 June 2020, notified Dr. XX, pursuant to art. 166, paragraph 5, of the Code, the initiation of the procedure for the adoption of the measures referred to in

Article 58, paragraph 2, of the Regulations, inviting the aforementioned holder 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, of the law n. 689 of 24/11/1981).

In particular, the Office, in the aforementioned deed, represented that:

- Dr. XX processed personal data and clinical documents relating to the aforementioned patient, outside the treatment purposes for which the aforementioned Company had authorized the same to access the company information tools.

Subsequently, Dr. XX entered the aforementioned data and documents in the slides subject of the presentation for participation in the aforementioned Award, without proceeding with an effective anonymization of the same;

- the information on the aforementioned slides, in particular, the patient's initials, age, details of hospitalizations and anamnesis, as well as the numerous photographic images have in fact made the patient identifiable, who, according to what is indicated by the relative lawyer in the documents in file, has not given its informed consent regarding this processing of personal data. In this regard, the consent to the processing of personal data carried out through the health dossier for the purpose of "epidemiological investigation and scientific research" cannot be considered an appropriate legal basis for the processing, as this consent has been issued for the treatments carried out by the aforementioned Company health care as data controller and not also with reference to those, possibly carried out as in the present case, by Dr. XX. This manifestation of will also refers to epidemiological investigations and scientific research activities that do not pertain to the treatment in question;

- Dr. XX has not requested any authorization from the aforementioned health company for the use of clinical data and documents of which it is the owner, directly acquiring a copy of the data and documents by accessing the information tools in use at the same health company as a doctor as well as a person authorized to process data.

In the aforementioned deed of 22 June 2020, the Office therefore considered that the making available, by Dr. XX, of the aforementioned personal data and diagnostic and photographic images, not anonymized, on the occasion of the aforementioned Award, without the informed consent of the interested party (patient) and without the authorization of the data controller (Azienda ULSS 9 Scaligera) has determined, against the professional, a violation of the basic principles of the treatment referred to in art. 5, 6 and 9 of the Regulations.

With a note dated 20 July 2020, Dr. XX asked to be heard by the Authority and sent her defense briefs, in which she reiterated

what had already been represented in the aforementioned note of 2 February 2020, and has, in particular, represented that:

"The work that led to the awarding of the" Best Clinical Case 2017 "award was presented in the medical-scientific field in a seminar reserved only for specialist surgeons, in a limited number";

"Regarding the reference to the fact that certain images would subsequently be published on the website of the Triveneta Society of Surgery, of this subsequent publication (if and as it happened) the writer did not know anything, nor did the writer have to authorize any form of dissemination "" Nobody imagined a publication could take place on the website of the Triveneta Society of Surgery ";

"The opportunity arose to examine the clinical case at the congress for the purpose of scientific sharing and also, given the complexity of the case itself, in order to obtain further useful insights on the treatment in progress in the direct interest of the patient. The identity was concealed with the use of the initial, as was the practice during the presentation of clinical cases. The remaining elements (anamnesis, sex, age and timing) constitute the usual information suitable and necessary for the fruitful discussion of the clinical case among the scientific community. In any case, they do not allow to trace the subject, guaranteeing its non-identifiability. The lack of such elements in the discussion of the case would render the work useless. (...) The radiological images - whose original files contain the patient's data - had been purposely anonymized ";

"The authorization to use the logo was not requested since it is a clinical case of particular scientific interest and related to the company's activity, in accordance with the convention practice in the medical-scientific field. There appears to be no regulation at the time ".

In relation to the request of Dr. XX, on 24 November 2020, at the Office of the Guarantor, pursuant to Articles 166, paragraphs 6 and 7, of the Code 18, paragraph 1, by law no. 689 of 11/24/1981 the hearing was held using telematic methods during which Dr. XX reiterated what had already been represented, specifying in particular that:

"The authorization to the Triveneta Society of Surgery to use the report was expressly issued until 31/12/2017 and no later than and that I had not been informed that the paper would be published on the website of the aforementioned company";

"The purpose of the presentation of the clinical case was to share information with my surgeon colleagues present at the exhibition of my report, to also obtain advice on the best care of the patient and in his primary interest, given the delicacy of the clinical history of the patient. predicted. I also specify that the patient, whose life was saved, was followed by the undersigned even after the presentation of the aforementioned clinical case ";

"The aforementioned photographs were taken to better explain the ways in which to proceed with the necessary medications for the patient for the benefit of the other health professionals who would have taken care of him during his hospitalization in the Scaligera Company. Together with the aforementioned photographs I had also drawn up a vademecum on how to proceed with the dressings. The photographs, as already reported in the documents transmitted, reside in the company information systems, but are not part of the patient's medical record ".

## 2. Outcome of the preliminary investigation.

The investigation carried out by the Office concerned the use by Dr. XX of the data and documents collected and drawn up during the hospitalization of a patient at the local social health unit no. 9 Scaligera for the creation of a paper aimed at participating in the "Best clinical case 2017" Award, sponsored by the Triveneta Surgery Society.

Pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (hereinafter, the "Regulation"), personal data must be "processed in a lawful, correct and transparent manner towards the interested party ( "Integrity and confidentiality") "and must be" adequate, relevant and limited to what is necessary with respect to the purposes for which they are processed ("data minimization") "(Article 5, paragraph 1, letter a) and c) of the Regulation).

The regulation on the protection of personal data provides - in the health sector - that information on the state of health can only be communicated to the interested party and can be communicated to third parties only on the basis of a suitable legal basis or on the indication of the interested party. subject to written authorization from the latter (Article 9 of the Regulations and Article 83 of Legislative Decree No. 196 of 30 June 2003 (Code regarding the protection of personal data - hereinafter the "Code") in conjunction with 'Article 22, paragraph 11, legislative decree 10 August 2018, n.101; see also general provision of 9 November 2005, available at [www.gpdt.it](http://www.gpdt.it), web doc. n. 1191411, deemed compatible with the the aforementioned Regulation and with the provisions of decree no.101 / 2018; see Article 22, paragraph 4, of the aforementioned Legislative Decree no. 101/2018).

The current legislation, forwards, expressly prohibits the dissemination of data suitable for revealing the state of health of the interested parties (Article 2-septies, paragraph 8 and Article 166, paragraph 2, of the Code).

With specific reference to the publication of clinical cases, the Code of medical ethics approved by the National Federation of orders of surgeons and dentists in 2014 (as amended in 2016 and 2017) provides that "the doctor insures (a) (i) the non-identifiability of the subjects involved in scientific publications or disclosures of clinical data and studies "(art. 11 -

Confidentiality of personal data).

#### 4. Conclusions.

In light of the aforementioned assessments, taking into account the statements made by the data controller during the investigation ☐ and considering that, unless the fact constitutes a more serious crime, anyone, in a proceeding before the Guarantor, falsely declares or certifies information or circumstances or produces false deeds or documents is liable pursuant to art. 168 of the Code "False statements to the Guarantor and interruption of the execution of the tasks or exercise of the powers of the Guarantor" ☐ the elements provided by the data controller in the defense briefs do not allow to overcome the findings notified by the Office with initiation of the procedure, however, as none of the cases provided for by art. 11 of the Guarantor Regulation n. 1/2019.

In particular, it is noted that Dr. XX processed personal data and clinical documents relating to the aforementioned patient, outside the treatment purposes for which the aforementioned Company had authorized the same to access the company information tools, without proceeding to request a specific authorization from the data controller and without carrying out an effective anonymization of data and documents.

As highlighted above, the information on the aforementioned slides, in particular, the patient's initials, age, details of hospitalizations and medical history, as well as the numerous photographic images made the patient identifiable. The latter, according to the results of the documents and indicated above, did not give the professional his informed consent regarding this processing of personal data, not being able to qualify, as the legal basis for the processing, the consent given to the Company for treatments aimed at "epidemiological investigation and scientific research" carried out through the company health dossier. This, as this consent was not issued with respect to the treatments carried out by Dr. XX, but rather by those put in place by the aforementioned health company, through the company health dossier, as the data controller.

Finally, it should be noted that from the documentation in file, it emerges that Dr. XX has not requested any authorization from the aforementioned Company for the use of clinical data and documents of which she is the owner, having acquired a copy of the data and documents used in the the aforementioned slides, after having directly accessed the information tools, in use by the same Company, as a doctor and person authorized to process personal data.

The provision of the aforementioned personal data and diagnostic and photographic images, not anonymized, on the occasion of the aforementioned Award, without the informed consent of the interested party and without the authorization of the data

controller (Azienda ULSS 9 Scaligera) has therefore determined a violation of the basic principles of the treatment referred to in art. 5, par. 1, lett. a) and c), 6 and 9 of the Regulation. The violation of the aforementioned provisions makes the administrative sanction provided for by art. 83, par. 5, lett. a) of the Regulations.

In this regard, however, it should be noted that the registration form for the aforementioned Award does not contain any authorization by Dr. XX for the publication of the aforementioned slides on the website of the Triveneta Society of Surgery.

Given that the aforementioned slides have been removed from the site of the Triveneta Society of Surgery and that Dr. XX has been the subject of disciplinary proceedings regarding the facts covered by this procedure, the conditions for the adoption of corrective measures do not exist. referred to in art. 58, par. 2, 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, par. 1, lett. a) and c), 6 and 9 of the Regulations, caused by the conduct put in place by Dr. XX is subject to the application of a pecuniary administrative sanction pursuant to art. 83, paragraph 5, lett. a) of the Regulations.

It should be considered 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 single 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 pecuniary sanction imposed, by reason of the seriousness of the conduct and according to 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. 85, par. 2, of the Regulation in relation to which it is noted that:

- the data processing concerned information on the health of a patient (Article 83, paragraph 2, letters a) and g) of the Regulation);
- the processing of the data subject's data took place as part of an opportunity to share scientific knowledge in the medical community (Article 83, paragraph 2, letters b) and k) of the Regulation);



- the registration form for the aforementioned Award signed by Dr. XX does not contain any authorization from the same for the publication of the aforementioned slides on the website of the Triveneta Society of Surgery (Article 83, paragraph 2, letter b) of the Regulations);
- the procedure described in the "Regulations for the granting of patronage and use of the logo of the company ulss 9 Scaligera di Verona" (Resolution of the General Manager No. 128 of February 16, 2017), was adopted after the presentation of the application for participation in the award by Dr. XX (dated 23 January 2017) and concerns the use of the company logo and not the procedures for obtaining the authorization of the Company to use the information it processes as owner, after anonymization, for scientific dissemination purposes (Article 83, paragraph 2, letter b) of the Regulations);
- the type of treatment in question presents elements of complexity in order to identify the correct methods of anonymization of patient data such as to have requested, after the event, the promotion by the Veneto Region of a code of conduct for the use of data for educational purposes and scientific publications, which was recently approved by the Authority (provision of 14 January 2021) (Article 83, paragraph 2, letter b) of the Regulation).

Due to the aforementioned elements, assessed as a whole, 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 € 5,000.00 (five thousand) for the violation of Articles 5, par. 1, lett. a) and c), 6 and 9 of the Regulations, as an administrative fine withheld, 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, also in consideration of the potential number of interested parties and the type of personal data subject to unlawful processing.

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 Dr. XX, for the violation of Articles 5, par. 1, lett. a) and c), 6 and 9 of the Regulations, within the terms set out in the motivation.

ORDER

pursuant to art. 58, par. 2, lett. i) and 83 of the Regulations to Dr. XX, C.F. XX, domiciled at the lawyer XX (XX), to whom it has

given a mandate for this proceeding, to pay the sum of 5,000.00 (five thousand) euros as a pecuniary administrative sanction for the violations indicated in this provision, according to the methods indicated in the annex, within 30 days from notification of 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 30 days, an amount equal to half of the sanction imposed.

INJUNCES

to the aforementioned Company, to pay the sum of € 5,000.00 (five thousand), according to the methods indicated in the annex, within 30 days of notification of this provision, under penalty of the adoption of the consequent executive acts pursuant to art. 27 of the law n. 689/1981. In this regard, it is recalled that the offender has the right to settle the dispute by paying - again according to the methods indicated in the annex - of an amount equal to half of the sanction imposed, within 30 days from the date of notification of this provision, pursuant to art. 166, paragraph 8, of the Code (see also Article 10, paragraph 3, of Legislative Decree no. 150 of 1/9/2011);

HAS

pursuant to art. 166, paragraph 7, of the Code, the full publication of this provision on the website of the Guarantor and believes 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.

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, April 15, 2021

PRESIDENT

Stanzione

THE RAPPORTEUR

Ghiglia

THE SECRETARY GENERAL

Mattei