[doc. web n. 9675228]

Order injunction against Eurosanità s.p.a. - April 21, 2021

Record of measures

n. 148 of 21 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");

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

GIVEN the legislative decree 30 June 2003, n. 196 containing the "Code regarding the protection of personal data, containing

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");

the free circulation of such data and which repeals Directive 95/46 / EC (hereinafter the "Code");

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, Dr. Agostino Ghiglia;

**WHEREAS** 

1. The violation of personal data.

The Eurosanità s.p.a company, which manages the Villa Stuart nursing home, has notified a violation of personal data, in

relation to the delivery, via e-mail, to a patient, of documentation containing the report of the urinalysis of a another patient, declaring that the violation was caused by a material error of the staff and not by a malfunction of the computer system and / or the network and / or a failure to protect the file (communication July 26, 2019).

## 2. The preliminary activity.

In relation to what was communicated by the Company, with deed dated 12 November, prot. n. 003885, was initiated, pursuant to art. 166, paragraph 5, of the Code, a procedure for the adoption of the measures referred to in art. 58, par. 2 of the Regulations, towards the same Company, inviting it to produce defensive writings or documents to the Guarantor or to ask to be heard by the Authority (Article 166, paragraphs 6 and 7, of the Code, as well as Article 18, paragraph 1, I. N. 689 of November 24, 1981).

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

- "The regulations on the protection of personal data provide in the health field 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 interested party itself subject to written authorization from the latter (Article 9 of the Regulations and Article 84 of the Code in conjunction with Article 22, paragraph 11, Legislative Decree 10 August 2018, n. general of 9 November 2005, available at www.gpdt.it, web doc. n.1191411, deemed compatible with the aforementioned Regulation and with the provisions of decree n. Legislative Decree no. 101/2018) ";
- "The Regulation also establishes that personal data must be" processed in such a way as to guarantee adequate security (...), including protection, by means of adequate technical and organizational measures, from unauthorized or unlawful processing and from loss, from accidental destruction or damage ("integrity and confidentiality") "(Article 5, paragraph 1, letter f) of the Regulation)".

That said, with the aforementioned deed of 12 November 2019, the Office deemed that the Company carried out, by sending a report via e-mail to a person other than the interested party, a communication of data relating to health, in absence of a suitable legal basis and, therefore, in violation of the basic principles of the processing referred to in Articles 5 and 9 of the Regulations.

With a note dated 2 December 2019, the Company sent its defense briefs, in which, in particular, it was specified that:

a) "the analysis carried out shows that the data subject to the violation refer to a single patient (Ms XX) and consist of personal

data and data relating to health, limited to only one of the tests (specifically urinalysis ) carried out by the patient and therefore not referable to her general state of health ";

- b) "in relation to the duration of the violation it is specified that the fact is limited to an isolated episode";
- c) "this is a purely material error of the staff previously trained and trained as required by the relevant legislation";
- d) "a formal communication was made, pursuant to art. 34 GDPR 2016/679, to the person concerned, to communicate the incident and at the same time the measures adopted by the data controller. The person directly concerned thanked the owner, reiterating the diligence, seriousness and attention shown, (...) showing the absence of injury to his person ";
- e) "all the staff of the facility have been previously and adequately trained through an intensive course" (inclusive) "of the operating procedures and obligations required by the regulations for communicating health data by e-mail") "carried out in class with final test to verify the learning of the treated contents";
- f) "An internal investigation was promptly opened by the DPO to reconstruct what happened (..); from a reconstructive analysis carried out with the subjects involved it emerged that, accidentally, during the process of printing, signing and scanning of the analyzes carried out on the same working day, two sheets containing the urine analysis of Ms XX, were accidentally scanned with the sheets relating to the analyzes of Mrs. XX ";
- g) "following the ascertainment of the accidental nature of the violation, caused by a purely material and unsystematic error, the Operations Director of the structure summoned the person in charge of the incident in order to carry out a coaching session to retrace all the phases of the procedure in place at the Structure. It was specified that any recurrence of the incident will result in disciplinary measures (...) "and" at the same time a communication was made to all the staff of the laboratory analysis of the structure, to reiterate greater attention in the management of clinical documentation ";
- h) "measures have been taken to simplify the procedure for sending reports-online", eliminating, from the operating procedure, "the step concerning the printing and subsequent scanning of documents, the cause of the material error";
- i) the purchase of dedicated software was also envisaged (...), of which the DPO "has ascertained compliance [...] with current European and national legislation"; "The system provides that at the time of acceptance the patient is asked whether or not to take advantage of the opportunity to consult online the answers of the tests performed. In case of acceptance and after the signing of the forms required by current legislation, the patient will be issued a code and a link which, once the exams are ready, will allow him to connect (for a limited period of time i.e. 30 days) directly to the Portal of the Structure. The patient can

use the password, received separately via sms on his mobile phone, in order to view and / or print his exams ".

## 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"), following the examination of the documentation acquired as well as the declarations made to the Authority during the procedure, that the Company has made a communication of data relating to health in the absence of a suitable legal basis, in violation of the basic principles of the treatment referred to in Articles 5 and 9 of the Regulations.

## 4. Conclusions

In light of the aforementioned assessments, taking into account the statements made by the data controller during the investigation, it is noted that the elements provided by the same in the defense briefs, although worthy of consideration, do not allow to overcome the findings notified by the Office with the act of initiation of the procedure and are insufficient to allow the filling of the procedure, since none of the cases provided for by art. 11 of the Guarantor Regulation n. 1/2019.

The preliminary assessments of the Office are therefore confirmed and the unlawfulness of the processing of personal health data carried out by the Company is noted, in violation of Articles 5 and 9 of the Regulations.

In this context, considering, however, that the conduct has exhausted its effects - also considering that the Company has provided assurances regarding the improvement actions undertaken in order to avoid the repetition of the incorrect conduct - the conditions for the "adoption of further corrective measures by the Authority, pursuant to 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. I and 83 of the Regulation; art. 166, paragraph 7, of the Code).

The violation of articles 5 and 9 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 the pecuniary administrative sanction pursuant to art. 83, 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 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 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 it is noted that: the data processing carried out by the Company concerns data suitable for detecting information on the health of a single data subject, relating to a single examination (Article 83, paragraph 2, letters a) and g) of the Regulation);

the tenuousness of the fact, given that the episode was accidental and caused by human error (Article 83, paragraph 2, letter b) of the Regulations);

the Authority became aware of the violation following the notification made by the data controller who also informed the interested party of the incident and no complaints or reports were received on the incident (Article 83, paragraph 2, letter h) of the Regulation);

the Company collaborated with the Authority during the investigation and this proceeding (Article 83, paragraph 2, letter f) of the Regulations);

the data controller promptly took action to remedy the incident also through the introduction of simplification measures for the online report submission procedure (Article 83, paragraph 2, letter c) and d) 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 (five thousand) for the violation of Articles 5 and 9 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.

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

the violation of articles 5 and 9 of the Regulations, declares the unlawfulness of the processing of personal data carried out by the Company under the terms set out in the motivation;

ORDER

to the Eurosanità s.p.a company, with registered office in Rome, Piazza dei Caprettari 70, Tax Code / VAT number: 06726891002, in the person of the pro-tempore legal representative, pursuant to art. 58, par. 2, lett. i) and 83 of the Regulations, as well as art. 166 of the Code, to pay the sum of 5,000.00 (five thousand) euros as a pecuniary administrative sanction for the violation referred to in this provision, according to the methods indicated in the annex, within 30 days from the 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, in the event of failure to settle the dispute pursuant to art. 166, paragraph 8, of the Code, 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.

HAS

the publication of this provision on the website of the Guarantor, pursuant to art. 166, paragraph 7, of the Code; the annotation of this provision in the internal register of the Authority - provided for by art. 57, par. 1, lett. u), of the Regulations, as well as by 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 - relating to violations and measures adopted in accordance with art. 58, par. 2, of the same Regulation.

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 21, 2021

**PRESIDENT** 

Stanzione

THE RAPPORTEUR

Ghiglia

THE SECRETARY GENERAL

Mattei