

Injunction against the Giuliano Isontina University Health Authority - 24 June 2020

Register of measures

no. 106 of 24 June 2020

THE GUARANTOR FOR THE PROTECTION OF PERSONAL DATA

IN today's meeting, which was attended by Dr. Antonello Soro, president, Dr. Augusta Iannini, vice-president, Dr. Giovanna Bianchi Clerici and Prof. Licia Califano, members and Dr. Giuseppe Busia, general secretary;

HAVING REGARD TO Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, concerning the protection of natural persons with regard to the processing of personal data, as well as the free movement of such data and repealing Directive 95/46/ CE, "General Data Protection Regulation" (hereinafter, "Regulation");

HAVING REGARD TO Legislative Decree 30 June 2003, n. 196 containing the "Code regarding the protection of personal data, containing provisions for the adaptation of the national legal system to Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, relating to the protection of natural persons with regard to the processing of personal data, as well as to the free movement of such data and which repeals Directive 95/46/EC (hereinafter the "Code");

CONSIDERING the law n. 689/1981 and subsequent amendments and additions, with particular reference to art. 1, paragraph 2;

GIVEN the report according to which the company GE Medical System Italia S.p. to. (hereinafter GEMSI), which supplies equipment for the acquisition of CT diagnostic images, "would have extracted a copy of the clinical documentation from the (...) CT scan in use at the Gorizia Hospital", belonging to the Health Assistance Company no. . 2 "Bassa Friulana-Isontina", Fiscal Code: 01162270316 - VAT No: 01162270316 – with registered office in Gorizia, Via Vittorio Veneto, n. 174 (hereinafter the "Company"), for the purpose of participating in a tender for the assignment of the supply of CAT scans and magnetic resonance imaging for the needs of the Healthcare Company of the Veneto Region;

HAVING REGARD to the request for information (prot. note n. 0016746 of 1 June 2018) from the Department of Public Freedoms and Health of this Authority, with which the Company was invited to provide any element and useful information in relation to what was reported;

HAVING ACKNOWLEDGED the letter dated 29 June 2018, with which the General Manager of the Company provided

feedback on the request;

GIVEN the further request (prot. note n. 0011330 of 2 April 2019) with which the Department of Health and Research, having found some discrepancies between the statements received in the preliminary investigation from the Company and those provided by the company GEMSI, asked the Company additional information elements;

HAVING ACKNOWLEDGED the Company's response note (Prot. n. 9/19 of 15 April 2019) with which the Director General of the same, among other things, highlighted the good faith of the same, declaring that the healthcare professional, to which presence the extraction of the radiological images was carried out, allowed access "in the erroneous belief that GEMSI was already in possession of due authorization to extract the requested images"..."moreover Gumsi represented to be the latter [access] aimed at recovering allegedly deteriorated images, and provided the doctor with very precise and detailed data with the requested image, thus inducing him to believe that the vaunted authorization really exists for this very reason";

HAVING REGARD to note no. 29273/125488 of 30 August 2019 of the Department of Health and Research, which defined the procedure, the reasons for which must be understood as fully referenced herein, in which it is ascertained that: "[...] GEMSI had access to information on the health of some patients of the Health Care Company no. 2 "Bassa Friulana-Isontina" and has carried out a treatment (extraction, anonymization and pseudonymization through the "Anonymous maker" software) of the same data, in order to produce the documentation required in the technical annexes of the tender of the Veneto Region to participate in the tender contract for the supply of CT and magnetic resonance equipment for the health authorities of the aforementioned Region. Therefore (..) the conduct put in place by the same (Company) has led to a "communication" of personal data relating to the health of some identified subjects, in the absence of an adequate regulatory prerequisite (articles 11 and 20 of the Code, in force at moment in which the facts object of the report occurred);

CONSIDERING that the facts covered by the report occurred in May 2017, on a date, therefore, prior to that on which Regulation (EU) 2016/679 became applicable (May 25, 2018) and that, therefore, to the processing of data personal data in question, the Code regarding the protection of personal data is applied in the version prior to the reformulation of the same made by means of Legislative Decree no. 101/2018;

HAVING REGARD TO the deed of 10 September 2019 (prot. n. 0030459) with which the Guarantor challenged the Health Care Agency no. 2 "Bassa Friulana-Isontina" Fiscal code: 01162270316 - VAT number: 01162270316 – with registered office in Gorizia, Via Vittorio Veneto, n. 174, in the person of the pro-tempore legal representative, the violation of the provision

referred to in article 20 of the Code, sanctioned by article 162, paragraph 2-bis of the same Code, for having communicated health data in the absence of an adequate prerequisite legislation and thus putting in place an unlawful processing of personal data;

DETECTED from the administrative report prepared by the Office, pursuant to art. 17 of the law of 24 November 1981 n. 689, that the reduced payment pursuant to art. 16 of law 689/81;

HAVING REGARD to the defense brief, presented pursuant to art. 16 of the law of 24 November 1981 n. 689, with which the Company highlighted that it had been "totally unaware of the further purposes and purposes for which the company (...) had extrapolated the same data" and that it was not aware "that Gemi had proceeded with the extraction (..) for completely selfish and commercial purposes (...), such as precisely the participation in a tender for the supply of CT and MRI equipment for the Veneto and Lombardy regions", being certain that "the 'extraction in comment (..) was part of the ordinary performance of the full risk maintenance service that GE offers for the diagnosis and/or resolution of a possible fault or to carry out checks on the status of the monitoring system". "Furthermore, given the fact that GEMSI is precisely a leading supplier in the sector and that there have been numerous relationships with this company for some time now, the Healthcare Authority has fully relied on the latter's loyalty and professionalism in the treatment , of the personal data owned by the A.A.S. no. 2". The Company, after recalling the reasons that had led it into error, already highlighted in the note of April 15, 2019, represented that "the sanctioned communication was somewhat limited as the extracted images were seen unencrypted and therefore with the complete identification data of the patient to whom they referred, exclusively by the GE technicians who extracted and subsequently anonymized the images themselves, as well as, at least as regards the second extraction by the healthcare professional involved", all named subjects authorized to process, "bound by their respective employers of work to a bond of secrecy the violation of which entails inevitable sanctions, not only disciplinary". In closing, the Company, in relation to the present sanctioning procedure, has requested, mainly, the archiving and, subordinately, the application of the statutory minimum;

CONSIDERING that the arguments put forward by the Company are not suitable to accept the requests formulated in the defense brief. In fact, with reference to the error made by the healthcare operator, an employee of the Company, who made the communication in question, "not authorized by the data controller and induced by misleading behavior by GEMSI personnel and such as to influence the good faith of the doctor", it should be noted that according to consolidated jurisprudence (Cass.

Civ. section I of 21 February 1995 n. 1873; Cass. Civ. section II of 13 March 2006, n. 5426), for the application of the art. 3 of the law n. 689/1981 it is necessary that the good faith or the error, in order to be excusable, are based on a positive element, extraneous to the agent and capable of determining in him the conviction of the legitimacy of his behavior. This positive element must not be remediable by the interested party with the use of ordinary diligence. In this case, the Company could have diligently ascertained, through the personnel in charge, whether or not GEMSI was entitled to access the health data detected through the medical equipment, thus avoiding communicating the aforementioned data to unauthorized parties . Furthermore, the fact that GEMSI's technicians had been designated as data processors by GEMSI itself - as data controller appointed by the Company - is not relevant in the present case, since the treatments concerning the extraction of data , the subsequent operations and their use (participation in the tender and consequent defense in court) pursued the Company's own purposes and were therefore not attributable to those for which this company had been designated as data controller by the Company;

NOTING that, on the basis of the considerations referred to above, the Company, in the person of the pro-tempore legal representative, as data controller, appears to have committed the violation of the provision pursuant to art. 20 of the Code sanctioned by art. 162, paragraph 2-bis, of the same Code, for having carried out unlawful processing of personal data, communicating health data without an adequate legal basis, as specified above;

CONSIDERING the art. 162, paragraph 2-bis of the Code, which punishes the violations indicated in art. 167, including the violation relating to art. 20 of the same Code with the administrative sanction of the payment of a sum from Euro 10,000.00 (ten thousand) to Euro 120,000.00 (one hundred and twenty thousand);

CONSIDERING that, for the purposes of determining the amount of the pecuniary sanction, it is necessary to take into account, pursuant to art. 11 of the law n. 689/1981, of the work carried out by the agent to eliminate or mitigate the consequences of the violation, the seriousness of the violation, the personality and economic conditions of the offender;

CONSIDERING that, in relation to the seriousness of the violation, the treatment, although having concerned health data, consisted in the communication of copies of diagnostic images acquired using CAT equipment, referring to some identified patients of the Company, only to the GEMSI technicians , who proceeded with the extraction and subsequent anonymization of the images themselves, as well as that the extraction of the data took place without any express or formal authorization from the owner or designated internal managers;

CONSIDERING, also, that with regard to the work performed by the agent to eliminate or mitigate the consequences of the violation, the Company has maintained a collaborative conduct with the Guarantor, promptly offering its willingness to provide the clarifications requested at all stages of the proceeding;

CONSIDERING, therefore, on the basis of the aforementioned elements evaluated as a whole, that it is necessary to determine, pursuant to art. 11 of the law n. 689/1981, the amount of the fine provided for by art. 162, paragraph 2-bis of the Code, to the minimum amount of 10,000.00 (ten thousand) euros for the violation of art. 20 of the same Code;

HAVING REGARD to the documentation in the deeds;

HAVING REGARD TO the observations made by the general secretary pursuant to art. 15 of the Guarantor's regulation n. 1/2000, adopted with resolution of 28 June 2000;

SPEAKER Dr. Giovanna Bianchi Clerici;

ORDER

to the Giuliano Isontina University Health Authority, Tax Code and VAT number 01337320327, with registered office in Trieste, Via Costantino Costantinides 2, in the person of its pro-tempore legal representative, which, in implementation of the provisions of art. 11 of the law of 17 December 2018, n. 27 of the Friuli Venezia Giulia Region, took over all the active and passive relationships of the Health Assistance Agency no. 2 "Bassa Friulana-Isontina", suppressed with effect from 1 January 2020, to pay the sum of 10,000.00 (ten thousand) euros provided for by art. 162, paragraph 2-bis of the Code, as a pecuniary administrative sanction for the violation of the provision pursuant to art. 20 of the same Code for having communicated data on health without a suitable legal basis and thus putting in place an illicit treatment of personal data;

ENJOYS

to the same Company to pay the sum of Euro 10,000.00 (ten thousand) according to the methods indicated in the attachment, within 30 days of notification of this provision, under penalty of adopting the consequent executive acts pursuant to art. 27 of the law of 24 November 1981, n. 689.

Pursuant to articles 152 of the Code and 10 of Legislative Decree no. 150/2011, opposition to this provision may be lodged with the ordinary judicial authority, with an appeal lodged with the ordinary court of the place where the data controller has his residence, within the term of thirty days from the date of communication of the provision itself or sixty days if the appellant resides abroad.

Rome, 24 June 2020

PRESIDENT

Soro

THE SPEAKER

Cleric Whites

THE SECRETARY GENERAL

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