SEE ALSO: Newsletter of January 24, 2023

[doc. web no. 9844989]

Corrective and sanctioning measure against the Western Friuli University Company - 15 December 2022*

*The provision was challenged before the Court of Pordenone; the Court ordered the suspension of the executive effectiveness of the provision as a precautionary measure.

Register of measures

no. 415 of 15 December 2022

THE GUARANTOR FOR THE PROTECTION OF PERSONAL DATA

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

HAVING REGARD TO Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data, as well as on the free circulation 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 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");

CONSIDERING the decree law of 19 May 2020, n. 34 law, converted with amendments into law 17 July 2020, n. 77, and, in particular, the art. 7 relating to predictive methodologies of the evolution of the population's health needs;

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

HAVING REGARD to the documentation in the deeds;

HAVING REGARD TO the observations made by the general secretary pursuant to art. 15 of the Regulation of the Guarantor n. 1/2000;

Speaker Dr. Agostino Ghiglia;

WHEREAS

1. Premise

It has been reported to this Authority that the resolution of the Friuli Venezia Giulia Region Council, no. 1737 of 20 November 2020 instructed General Practitioners (hereinafter also GPs) to validate, for the purpose of the pro rata payment of part of the variable remuneration, "through the regional IT portal, a list of users/assisted persons previously identified by the 'Health agency, according to its own (unknown) criterion, such as in conditions of complexity and comorbidity for the (apparent) purpose of statistical stratification by filling in computer files in which to report personal bio-humoral data, therapies, pathological status, family addresses, conditions/habits of life, etc.". Together with the report, a copy of the attachment to the aforementioned resolution was provided containing the "memorandum of understanding between the FVG Region and the trade union organizations of GPs for the regulation of relations for the two-year period 2020 -2021 and of the activities connected to the epidemiological emergency from Covid-19 ". The first of the objectives indicated in the aforementioned report concerns the "stratification, complexity and comorbidities at high risk of major complications from Covid-19 infections", with respect to which in the "notes" section of the report synthetic indications are provided on the preparation of the lists of patients to be submitted to the initiative medicine plans and on the ways in which they are downloaded, through the company Insiel, "from the portal of continuity of care" and then made available to the health authorities.

It was also reported that the aforementioned resolution would require GPs to communicate data on the health of their patients without the possibility for them to verify "whether the Healthcare Company has [preventively] given consent" to the processing of their personal data for purposes of "statistical stratification", also highlighting how this specific discipline provides for "the anonymous transmission of data for statistical or administrative purposes".

2. The preliminary investigation

In relation to the above, the Office has launched a preliminary investigation (note of the XX, prot. n. XX) requesting the Friuli Venezia Giulia Region and another regional health agency for specific information elements in order in particular to:

the initiatives taken in order to ensure that the treatments necessary to carry out the aforesaid initiative medicine activities were implemented in compliance with the regulations on the protection of personal data, with particular reference to what is indicated in the provisions of the Guarantor adopted on the matter (Opinion to the Council of State on the new ways of

allocating the health fund among the regions proposed by the Ministry of Health and based on population stratification, of 5 March 2020, web doc. n. 9304455, opinion on the draft law of the Autonomous Province of Trento containing specific provisions on proactive medicine, of 8 May 2020, web doc. No. 9344635, opinion on the draft regulation relating to the implementing provisions of the Trentino provincial law for proactive medicine in the provincial health service, of 1 October 2020, web doc. 9469372, provision dated 17 December 2020, web doc. n. 9529527; provisions dated 24 February 2022 n. 63, 64, 65, 66, 67, 65, 68, 69 and 70, doc. web no. 9752177, 9752221, 9752260, 9752299, 9752410, 9752433, 9752490 and 9752524);

the purposes pursued with the data processing envisaged by the report attached to the aforementioned resolution, and for each of them the relative legal basis of the processing, as well as the relative owners and managers, pursuant to articles 9, 24 and 28 of the Regulation;

if the treatment, although aimed at the pursuit of treatment purposes, is not strictly necessary for this purpose, the methods of prior acquisition of the informed and explicit consent of the interested parties, pursuant to art. 9, par. 2, lit. a) of the Regulation;

the description of the personal data flows indicated in the report attached to the aforementioned resolution, specifying whether the processing concerned health data or anonymous and aggregated data;

the impact assessment carried out, pursuant to art. 35 of the Regulation, considering that we are dealing with large-scale processing of particular categories of personal data and therefore at high risk.

The Region, with note of the XX prot. no. XX stated that: “as regards, in particular, objective n. 1 [of the recalled understanding] relating to the validation [of the] list of clients in conditions of complexity and comorbidity (target population) for the purpose of making the Lists available on the Continuity of Care Portal, the General Managers of the Company pertaining to the individual are invited GP to provide INSIEL as soon as possible, as for previous years, the operational indication to make the relative functions visible only for those patients who have given their specific consent to the communication of their data to their GP”. It was also specified that, for this purpose, "ARCS has provided the methodological support for the preparation of the algorithm for defining the lists of fragile subjects belonging to the RUB 4 and 5 categories. The tool used by ARCS for the preparation of the algorithm does not contains patient name information but an anonymous numeric identifier, subject to change every 6 months. Within the syntactic rules used, an extraction filter was inserted for subjects belonging to the RUB 4 and 5 categories who had already given their consent to visibility by the GP. (...). The lists, already purged, are published by

INSIEL, on behalf of the Healthcare Companies, for each GP who, being able to identify their patients, proceed with the validation of the same".

With reference to the aforementioned personal data processing operations, the Region declared that "the identification of assisted persons and their inclusion in the lists finds the legal basis in the generic consent provided by the interested party and relating to the visibility by the GP".

In relation to the need to draw up an impact assessment, it was also represented that "no initiative medicine activity can, therefore, be recognized in the activity described above and, consequently, no specific risk assessment activity is necessary primarily on the part of the Region, which in any case never has access to personal data, nor by the regional health authorities".

The Office, in acknowledging what was indicated by the Region and the results of a similar investigation initiated against another Regional Health Authority, i.e. that the treatment in question had involved all the regional health authorities, carried out an additional investigation against the latter, including the Western Friuli Healthcare Authority (hereinafter also ASFO or Company) and the Friuli Venezia Giulia Region (note of the XX, prot. n. XX).

In particular, the Office asked the Region and Insiel S.p.a. to indicate the specific databases from which the information used to carry out the aforementioned activity of stratification of the assisted was extracted and the related data controllers and processors; the type of information and clinical documents that have been processed for the stratification activity, highlighting any techniques used to ensure the non-identifiability, even indirectly, of the interested parties; the legal basis of the aforementioned treatments; the number of clients involved in the aforementioned stratification activity.

In response to the aforementioned request for information, the Friuli Venezia Giulia Region, with a note of the XX (prot. n. XX), declared, in particular, that:

- "the undersigned, as a superordinate body, manages the governance of the health infrastructure within the scope of its tasks of health planning, verification of the quality of care and evaluation of health care. Healthcare companies, for the area of their competence, are the owners of the data contained in the databases of the infrastructure pursuant to Article 24 of the GDPR. ARCS is the Regional Health Coordination Company and carries out support and liaison activities between the Region and the Companies. Insiel S.p.A. is the in-house company appointed by the companies responsible pursuant to art. 28 of the GDPR";
- "to deal with the spread of infections and above all to prevent improper access to hospital facilities, in compliance with DL

23/2020 and DL 34/2020, it promoted vaccination by activating GPs on the basis of the agreement referred to in resolution no. 1737/2020";

- "In this process, the Region, signatory of the AIR agreement with the GPs, had the role of organization and government by delegating to the Healthcare Companies and to the GPs, holders for their respective areas of competence of the health data of their patients, as well as to the appointed, the implementation of the program envisaged by the AIR";

- "The cohort of subjects thus identified by each doctor therefore becomes the basis for the evaluation of subsequent activities: (...) if it has not already been compiled, as required by current legislation (The concept of of a synthetic health profile or "patient summary", which is the electronic health and social document drawn up and updated by the general practitioner or pediatrician of free choice, which summarizes the patient's clinical history and his known current situation. is to favor the continuity of care, allowing a rapid classification of the patient at the time of contact with the NHS)";

- "the lists made available to GPs, as expressly indicated in the AIR agreement, are defined using the tool called ACG through the selection of patients to whom the system has assigned RUB 4 and 5 classes". In particular, it was shown that the "RUBs (Resource Utilization Bands) are synthetic measures of the degree of care complexity of a population understood in terms of expected consumption of resources" and that they "classify the level expected absorption of health resources, (...) and do not provide an economic quantification or a description of the type of expected resources".- The algorithm of the "Johns Hopkins ACG System is implemented (...) by Insiel which obtains the results" , i.e. the list of patients that was provided to each general practitioner (GP), who, in relation to their patients, could have modified or validated it on the basis of the information available to them.

Insiel S.p.a., with a note dated XX (prot. n. XX), as head of the regional healthcare companies, declared, in particular, that:

− "The information used to perform the requested processing activity was extracted from the regional data warehouse. Each Healthcare Company (ASU GI, ASU FC, AS FO) is the Data Controller of the personal data of its clients contained in the aforementioned regional data warehouse".

The ARCS represented that Insiel would have fed the "Johns Hopkins ACG System" with input datasets, containing information on codified diagnoses, drugs taken, costs incurred by the SSR, age and gender (cf. ARCS note of the XX, protocol XX).

According to what was declared in the deeds, the processed data were pseudonymized through the application of random numerical codes elaborated by ARCS for the attribution "of the filters on the Rub 4 and 5 classes and on the presence of

consent to view the health record" and made available to the Insiel company. This company, "In order to communicate the data to each GP in relation to its patients, added the tax code, surname and name to the extraction and made the list of patients available on the regional application Portal of Continuity of Care according to the following path: − GP tax code − GP regional code − assisted tax code − assisted surname − assisted name − age class − integrated care plan − pneumococcal vaccines − ACG-RUB".

Finally, in relation to the number of patients involved in the aforementioned treatment operations, it was represented that the list consists of over 40,000 (of which 9,487 pertaining to ASFO).

In relation to what was declared in the documents, the Office, with a note of the XX (prot. n. XX), requested information from the health authorities of the Friuli Venezia Giulia Region, including ASUGI, so that the databases from which the extracted the information used to carry out the aforementioned activity of stratification of the assisted; the legal premise on the basis of which ARCS is allowed to access, in the forms mentioned above, the data of the clients of these companies, and Insiel is allowed to process the data through the use of the "Johns Hopkins ACG System".

In response to the aforementioned request for information, the Company, with a note of the XX (prot. n. XX), represented, in particular, that:

- "with note XX of the XX, the Central Health Directorate (DCS) of the Friuli Venezia Giulia Region, transmitted to this Company the resolution of the regional council n. XX of the XX. This note, reiterating what was established in the resolution (point 3 of the operative part), prescribed that the regional health authorities were "obligated to follow up on the implementation obligations of the 2020-2021 Agreement in compliance with the provisions contained therein and in accordance with the national and regional provisions in matter";
- "From the aforementioned documents it appears that the treatments subject to the current request for information and, in particular, the stratification of clients through the application of the ACG algorithm and the consequent elaboration of lists of clients falling within the so-called RUB 4 and RUB 5, were carried out by ARCS and Insiel S.p.A., an in-house company of the Friuli Venezia Giulia Region, on a regional mandate";
- "The role of this Company was exclusively to provide Insiel S.p.A. "the operational indication to make the functions visible [...] only for assisted persons who have given specific consent to the communication of their data to their GP", and verification of the achievement of the objective by the GPs and consequent payment of the incentives to GPs, on the basis of the percentage

of achievement of the same";

- "As regards the legal premise on the basis of which ARCS and Insiel S.p.A. were allowed to to carry out the treatments in question, it is believed that the same can be identified in the DGR n. 1737/2020 mentioned and in the FVG regional law n. 22/2019 containing "reorganization of the levels of assistance, rules on health and social-health planning and programming and amendment to the Regional Law 26/2015 and to the Regional Law 6/2006".

In the light of these findings, the Office requested further information from the Region, Insiel S.p.a. and the regional health authorities regarding the specific databases through which Insiel fed the John Hopkins ACGsystem from which the information used to carry out the stratification activity of the patients in question was extracted, as well as to indicate whether the aforementioned databases of ownership of the individual healthcare companies correspond to those used by them to feed the ESF or, if not, to indicate from which databases (note of the XX, prot. n. XX).

The Friuli Venezia Giulia Region, with a note of the XX (prot. n. XX), specified that "GPs could have independently drawn up the aforementioned lists where the completion of the patient summary had been concluded, which has not yet happened. Therefore, given the particular moment of emergency, the writer has provided indications to the authorized and enabled subjects to give GPs the necessary technical support for the definition of the lists".

The Region also provided a note from Insiel S.p.a., of the XX (prot. n. XX), with which the Company indicated the databases used for the aforementioned activities, which also include those of the electronic health record.

In response to the aforementioned request for information, the Company represented that "its role was exclusively that of following up - in compliance with the resolution of the Regional Council n. 1737 of 20 November 2020 - to the implementation obligations of the Agreement 2020-2021 between the Friuli Venezia Giulia Region and the Trade Union Organizations of General Practitioners (GPs), in compliance with the provisions contained therein and consistently with the national and regional provisions on the matter ” (note of the XX).

In the aforementioned note, the Company also reiterated that it was "invited to provide Insiel S.p.A. "the operational indication to make the functions visible [...] only for assisted persons who have given specific consent to the communication of their data to their GP" [..]; it then verified the achievement of the objective by GPs, paying their related incentives. The purposes (planning and evaluation of health care) and means of processing (application of the ACG algorithm) to the databases present in the regional data wherehouse have, on the other hand, been entirely established at the regional level with the

aforementioned resolution".

3. The legislation on the protection of personal data and the specific regulation of the relevant sectors

According to the Regulation, "personal data" means "any information relating to an identified or identifiable natural person ("data subject"); an identifiable natural person is one who can be identified, directly or indirectly, with particular reference to an identifier such as a name, an identification number, location data, an online identifier or one or more characteristic elements of his physical identity, physiological, genetic, psychic, economic, cultural or social" (art. 4, point 1, of the Regulation).

Pseudonymisation means “the processing of personal data in such a way that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that this additional information is kept separately and subject to technical and organizational measures intended to ensure that such personal data are not attributed to an identified or identifiable natural person" (Cons. 26 and art. 4 (5) of the Regulation).

The legislation on the protection of personal data does not apply to "anonymous information, i.e. information that does not relate to an identified or identifiable natural person or to personal data made anonymous enough to prevent or no longer allow identification of the interested party” (see Cons. 26 of the Regulation and WP29 Opinion 05/2014 on Anonymisation techniques, adopted on 10 April 2014).

Anonymised data is such only if it does not in any way allow the direct or indirect identification of a person, taking into account all the means (economic, information, technological resources, skills, time) available to whom (owner or other subject) try to use these tools to identify a data subject. Anonymisation cannot be considered achieved through the mere removal of the personal details of the interested party or their replacement with a pseudonymous code. An anonymisation process cannot effectively be defined as such if it is not suitable for preventing anyone using such data, in combination with "reasonably available" means, from:

1. isolate a person in a group (single-out);

2. link anonymised data to data referable to a person present in a separate set of data (linkability);

3. deduce new information referable to a person from anonymised data (inference) (cf. Opinion 05/2014 - WP 216 on anonymisation techniques, adopted on 10 April 2014).

That said, the processing of personal data must take place in compliance with the established principles and additional rules of the Regulation and the relevant provisions of the Code.

In relation to the case in question, reference is made to the principles of lawfulness, correctness and transparency according to which personal data must be processed in a lawful, correct and transparent manner (Article 5, paragraph 1, letter a), of the Regulation ; see also Article 29 Data Protection Working Party, Opinion 03/2013 on purpose limitation of 2 April 2013).

More specifically, the Regulation provides for a general prohibition on the processing of particular categories of data, including those relating to the health of the data subjects, unless one of the particular exemptions from this prohibition pursuant to art. 9, par. 2 of the same Regulation.

In this regard, the cases in which:

- the interested party has given his explicit consent, except in cases where the law of the Union or of the Member States provides otherwise (Article 9, paragraph 2, letter a) of the Regulation);
- the processing is necessary for reasons of substantial public interest on the basis of Union or Member State law, which must be proportionate to the aim pursued, respect the essence of the right to data protection and provide for appropriate and specific measures to protect the fundamental rights and interests of the data subject (Article 9, paragraph 2, letter g) of the Regulation). In this case, the art. 2-sexies of the Code according to which "the processing of particular categories of personal data pursuant to article 9, paragraph 1, of the Regulation, necessary for reasons of significant public interest pursuant to paragraph 2, letter g), of the same article, are allowed if they are provided for by European Union law or, in the internal legal system, by provisions of law or regulation or by general administrative acts that specify the types of data that can be processed, the operations that can be performed and the reason for relevant public interest, as well as appropriate and specific measures to protect the fundamental rights and interests of the data subject";
- the processing is necessary for the purposes of preventive medicine or occupational medicine, assessment of the employee's ability to work, diagnosis, assistance or health or social therapy or management of health or social systems and services on the basis of Union or State law states or in accordance with the contract with a health professional (Article 9, paragraph 2, letter h) and par. 3 of the Regulation and 75 of the Code; provision of the Guarantor containing Clarifications on the application of the regulations for the processing of data relating to health in the health sector of 7 March 2019 doc. website 9091942).

With reference to the principle of transparency, the related information charges pursuant to articles 13 and 14 of the Regulation, according to which each treatment must be preceded by a suitable information also in order to allow the interested parties to exercise the rights due to them (art. 15-22 of the Regulation). This principle also requires that information and

communications relating to the processing of personal data be made in a concise, transparent, intelligible and easily accessible form, with simple and clear language (cons. 39 and 58 and art. 12 of the Regulation).

The Regulation also provides that "when a type of processing, when it involves in particular the use of new technologies, given the nature, object, context and purposes of the processing, may present a high risk for the rights and the freedoms of natural persons, the data controller carries out, before proceeding with the treatment, an assessment of the impact of the foreseen treatments on the protection of personal data. A single evaluation can examine a set of similar treatments that present similar high risks" (art. 35; Group art. 29 Guidelines n. 248 concerning "The assessment of the impact on data protection as well as the criteria for establishing whether a treatment" adopted in amended form on 4.10.2017).

In this regard, it should be noted, from the outset, that this requirement has not been waived by the emergency regulations adopted with reference to the pandemic context, as can be seen, for example, from the authorization provided by the Authority on the impact assessment carried out by the Ministry of Health with reference to the treatments carried out within the national contact tracing system - App Immuni (see provisions of 1 June 2020, 25 February 2021 and 24 November 2022), as well as the provisions adopted on the matter in the emergency context (see provisions of 13 May 2021, web doc. No. 9685332, of 13 January 2022, web doc. No. 9744496).

Noting that the initiative examined envisaged the extraction of data on the health of the patients from the Datawarehouse of the Company through the company Insiel SPA, an in-house ICT company of the Region, appointed as Data Processor, through the use of an algorithm provided by the regional agency for the coordination of health, the following is also highlighted.

This activity determines the collection and processing of health data in order to create, with reference to specific pathologies (which, in the case in question, are those that can expose the most fragile assistants to contracting more serious infections from SARS Cov-2) , a health risk profile of the person concerned, useful for implementing preventive interventions to take charge of the patient.

The activity of stratification of the health risk of the population is configured as an administrative activity prodromal to the care activity, consisting in taking charge of the patient, as it allows to classify the assisted persons considered to be at greater risk, in order to prepare in their compare an early and specific taking charge activity.

3.1 Stratification activities of the assisted population

With specific reference to the treatments carried out by health bodies for purposes of public interest, also in the light of what is

indicated by the Ministry of Health1 on the matter and supported by the Guarantor in the numerous provisions on the aforementioned subject, these treatment operations fall within the scope of the so-called "initiative medicine", even if addressed, in the present case, only to the emergency context.

This is because, through these treatments, a stratification of the patients of the Regional Health Service is carried out on the basis of information relating to the individual state of health, for the relative placement in health risk classes, in order to identify assistance models aimed at the active promotion of health interventions aimed at an early taking charge of them (see also the aforementioned opinion on the draft law of the Autonomous Province of Trento which contains specific provisions on self-initiated medicine, of 8 May 2020, web doc. n. 9344635, opinion on the draft regulation relating to the implementing provisions of the Trentino provincial law for initiative medicine in the provincial health service, of 1 October 2020, web doc. n. 9469372, provision against the USL Toscana Sud Est of 17 December 2020, web document No. 9529527, provisions no. 63, 64, 65, 66, 67, 65, 68, 69 and 70 of 24 February 2022 web document No. 9752177, 9752221, 9752260, 9752299, 9752410, 9752433, 9752490 and 9752524).

3.2. Patient care activities

With specific reference to the purposes of treatment and prevention, it should be noted that the Guarantor has already highlighted that such treatments must be considered additional and independent of those strictly necessary for ordinary treatment and prevention activities (Article 9, paragraph 2, letter h) of the Regulation), and therefore can only be carried out on the basis of the specific informed consent of the interested party (Article 9, paragraph 2, letter a) of the Regulation) (see ex multis, opinion on the draft law of the Autonomous Province of Trento which contains specific provisions on initiative medicine, of 8 May 2020, web doc. n. 9344635).

3.3. The treatments carried out through the electronic health record

It should also be noted that through the electronic health record (FSE) the purposes set out in the specific discipline of the sector can be pursued and in particular those of: a) diagnosis, treatment and rehabilitation; a-bis) prevention; a-ter) international prophylaxis; b) study and scientific research in the medical, biomedical and epidemiological fields; c) health planning, verification of the quality of care and assessment of health care (art. 12, 18 October 2012, n. 179, converted with amendments into law 17 December 2012, n. 221, and dpcm 29 September 2015, n. 178).

Among the aims that can be pursued through the ESF, therefore, the one relating to predictive or initiative medicine does not

appear. The legislator, in fact, even in the recent interventions carried out on the matter, has not extended this purpose among those that can be pursued through the ESF. The data accessible through the ESF, deprived of direct identification elements, may instead be processed by the Ministry of Health, also through interconnection with other data sources, for the purposes and with the methods that will be established by decree of the Minister of Health, which must be adopted with the opinion of the Guarantor, in compliance with the provisions of the Regulation, the Code, the Digital Administration Code and the guidelines of the Agency for Digital Italy on interoperability (Article 2-sexies, paragraph 1-bis) (see also opinions given by the Guarantor on 22 August 2022, n. 294 and 295 web doc. n. 9802752 and 9802729).

The fact that the interested party's consent has been given to the processing of data present in the EHR for treatment purposes does not therefore legitimize the subjects who access this information tool to process the information contained therein to outline specific health risk profiles of the interested party.

3.3. Statistical activity

Bearing in mind that during the preliminary investigation, reference was made to a "statistical stratification" activity, it should finally be noted that the processing of personal data, carried out for these purposes by subjects participating in the national statistical system (SISTAN), must in any case take place in compliance, not only with the pertinent provisions of the Regulation (articles 5, paragraph 1, letter c) and e) and 89) and of the Code (articles 2-sexies, paragraph 2, letter cc) and 104 et seq.), but also of the Deontological Rules for treatments for statistical or scientific research purposes carried out within the National Statistical System, Annex A4 to the Code, as well as the specific sector discipline referred to in Legislative Decree no. 322/1989, containing "Regulations on the National Statistical System and on the reorganization of the National Statistical Institute".

4. The disciplinary procedure

Following the aforementioned findings, the Office, with deed no. XX of the XX, notified the Western Friuli University Company, 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 Regulation, inviting the aforesaid holder to produce defense 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 law n. 689 of 11/24/1981).

In particular, the Office has detected the existence of elements suitable for configuring, by the Company, the violation of the

legislation on the protection of personal data in relation to the processing of personal data relating to health, albeit processed in a pseudonymized form, in the absence of a suitable legal prerequisite and, therefore, in violation of the principles applicable to the treatment referred to in articles 5, par. 1 lit. a), 9, of the Regulation, as well as of the art. 2-sexies of the Code; in violation of the principle of transparency, not having provided the interested parties with specific information regarding such processing of personal data as provided for by art. 14 of the Regulation; in violation of the owner's obligations regarding the impact assessment on the protection of personal data pursuant to art. 35 of the Regulation.

With the note of the XX, prot. no. XX, the ASFO sent its defense writings by advancing a formal request for a hearing.

In the aforementioned writings, the Company declared "to find the legal basis of the regional choices in the FVG law of 19 December 2019, n. 22", which establishes that "[...] the Regional Health Service activates innovative organizational methods of taking charge, based on proactivity and on initiative medicine", specifying (art. 4, paragraph 5) that "The activities for the social and health assistance are defined within the annual guidelines for the management of the regional health service". The Company then recalls that the latter, for 2020 (approved with Regional Decree No. 2195/2019), envisaged the need to "map and stratify the reference population on the basis of the complexity of the case mix, the risk of events and the fragility , using tools such as the Adjusted Clinical Groups (ACG) in order to optimize the appropriateness of management and interventions by levels of intensity and complexity".

The Company also represented that it and "the competent "Conventional Medicine" office never followed up on the regional invitation - concerning objective n. 1 of the Understanding 2020-2021- to provide Insiel S.p.A. "the operational indication of making the functions visible only for assisted persons who have given specific consent to the communication of their data to their GP" (see DCS note prot. n. XX of XX, annex I to the ASFO reply prot. n XX cit.)".

The Company specified that it had never "requested" Insiel "to take action in the aforementioned terms", however the aforementioned Company "with mere e-mail communication of the XX [...], directly prepared, already starting from the following twenty-four hours , the release of "an adaptation of the SCC [Continuity of Care System, ed.], as indicated in the Annex to resolution n._1737 of 11/20/2020, which consists of the list of GPs assisted in complexity and comorbidity (population target), to allow validation of the GP itself".

The Company then specified that "Insiel S.p.A., in this way, has complied with the provisions of Regional Government Decree no. 1737/2020 and the attached Agreement 2020-2021 between the FVG Region and the Union Representatives of GPs,

without acquiring the authorization of this Healthcare Company". In the light of these reasons, the Company declares that "it does not consider itself the owner of the treatment resulting from the stratification activity".

The Company, with subsequent communication of the XX, withdrew from the hearing.

5. Outcome of the preliminary investigation

Having acknowledged what is represented by the Company in the documentation in the deeds and in the defense briefs, in the light of the aforementioned regulatory framework and what emerged in the context of the information acquired from the Friuli Venezia Giulia Region, from Insiel s.p.a. and by ARCS the preliminary assessments of the Office are confirmed, within the limits set out in the following reasons.

5.1 Absence of a suitable legal basis for the treatment

The Company represented, in particular, to find the legal basis of the regional choices from which the treatments in question derive in the FVG regional law n. 22/2019, according to which "[...] the Regional Health Service activates innovative organizational methods of taking charge, based on proactivity and initiative medicine [...]" and "the activities for social and health assistance are defined [...] in the scope of the annual guidelines for the management of the regional health service. These annual lines for the year 2020 were approved with Resolution of the Friuli Venezia Giulia Region Council, no. 2195/2019 providing for the need to "map and stratify the reference population on the basis of the complexity of the case mix, the risk of events and frailty, using tools such as the Adjusted Clinical Groups (ACG) in order to optimize the appropriateness of the management and interventions by levels of intensity and complexity".

In this regard, it should be noted that the assumption of legitimacy of such processing cannot be found in the regulatory framework highlighted above and in particular in the DGR n. 2195/2019, which does not comply with the requirements of art. 2 sexies of the Code and does not indicate the subjects who can carry out the processing, the operations that can be carried out and the relevant public interest (see in this sense the opinion on the draft law of the Autonomous Province of Trento which contains specific provisions on initiative medicine, of 8 May 2020, web doc. No. 9344635, opinion on the draft regulation relating to the implementing provisions of the Trentino provincial law for initiative medicine in the provincial health service, of 1 October 2020, web doc. 9469372).

As already reiterated by the Authority also in the opinion to the Council of State, the profiling of the user of the health service, be it regional or national, determining an automated processing of personal data aimed at analyzing and predicting the

evolution of the health situation of the individual patient and any correlation with other elements of clinical risk (in this case, Sars Cov-2 infection), can only be carried out in compliance with specific requirements and adequate guarantees for the rights and freedoms of the interested parties (see art. 4, paragraph 1, no. 4 articles 13, paragraph 1, letter f); 14, par. 2, lit. g), 15, para. 1, lit. h) art. 21, par. 1 and 35, paragraph 3, lett. a) of the Regulation), or on the basis of a provision that has the requisites established by the regulations on the protection of personal data, referred to in the aforementioned article 2-sexies, paragraph 1, of the Code.

In this regard, it should be noted that the use of predictive medicine systems by the Ministry of Health has in fact been provided for by a specific regulatory provision, or by the aforementioned art. 7 of the so-called "Relaunch" decree (d.l. n. 34 of 2020), which expressly provides that the aforementioned Dicastery, within the scope of its institutional tasks and in particular, of the functions relating to general guidelines and coordination in the field of prevention, diagnosis, treatment and rehabilitation of diseases, as well as technical health planning and guidance, coordination, monitoring of the regional technical health activity, can process personal data, also relating to the health of the patients, collected in the information systems of the National Health Service, for the development of predictive methodologies of the evolution health needs (art. 7, paragraph 1, legislative decree n. 34/20). This article refers to a regulation, to be adopted with a decree of the Minister of Health, subject to the opinion of the Guarantor, in which personal data are identified, also relating to the particular categories of data that can be processed, the operations that can be performed, the methods for acquiring data from the information systems of the subjects who hold them and the appropriate and specific measures to protect the rights of the interested parties, as well as the retention times of the processed data (Article 7, paragraph 2).

Furthermore, with specific reference to the circumstance that only the data of those who have given their consent to consult the EHR would have been extracted from the Insiel company, taking into account the specific purposes pursued through the Dossier which do not include those of self-initiated medicine, it is represented that the consent expressed for the treatments carried out through the FSE cannot be considered a suitable prerequisite of lawfulness for the treatments in question carried out by the Company.

With specific reference to the circumstance that Insiel has extracted data on the health of patients from the Company's databases without the express authorization of the owner, implementing the aforementioned regional resolution, and that therefore the Company does not "consider itself the owner of this treatment ” specifies the following.

As highlighted by the Company itself, Insiel accesses the aforementioned database as data controller, from which it can be seen that the ownership of the treatment falls on the ASFO, ownership deriving from the provisions of the sector, since the health company is the only subject legitimated to process information on the health of patients on the basis of the current regulatory framework.

Moreover, this ownership is also recognized in the declarations in the documents of the Region (note of the XX, prot. n. XX) and of Insiel (note of the XX, prot. n. XX) to which the ASFO expressly refers with regard to the claims by the aforementioned bodies in relation to the databases from which the data were processed by Insiel (note of the XX).

It is also represented that, as highlighted in the 07/2020 Guidelines on the concepts of data controller and data processor of the EDPB of 7 July 2021, it is the task of the data controller, in this case the Company, to decide what the data controller must do in relation to personal data, who has the duty to comply with the instructions of the data controller, but also has the general obligation to comply with the sector legislation (paragraphs 139, 147). It is also up to the data controller to adopt the final decision approving the methods of carrying out the processing as well as requesting any changes (point 30 of the aforementioned Guidelines).

Although the Company has not authorized the treatment linked to the stratification of the assisted population through the processing of data present in the databases it owns, at the state of the records it does not appear that any initiative has been taken against the manager to prevent such treatment or to request its termination if he deemed it illegitimate.

It should also be noted that what the Company declared in the aforementioned note of the XX contradicts what it said in the note of the XX. In fact, while in the note of 1 April the ASFO declares that it has not provided any indications to Insiel on the implementation of the aforementioned regional resolution, since the aforementioned company acted autonomously, in the note of 28 January the same Company had acknowledged that its role was "exclusively to follow up - in compliance with the resolution of the Regional Council n. 1737 of 20 November 2020 - to the implementation obligations of the Agreement 2020-2021 between the Friuli Venezia Giulia Region and the Trade Union Organizations of General Practitioners (GPs), in compliance with the provisions contained therein and consistently with the national and regional provisions on the matter ” (incipit of the note).

In this regard, it should be reiterated that the fact that a third party, in the case in question represented by the Region, asks a data controller (Health Agency), also through the manager, to carry out processing operations on personal data with respect to

which this The latter is the owner, also indicating the methods, does not exclude that it is up to the latter, also on the basis of the principle of accountability (articles 5, paragraph 2 and 24 of the Regulation), to evaluate the legitimacy of the request and, in particular, the existence of an appropriate legal basis for carrying out the requested processing operations, especially since, in the present case, the aforementioned operations concerned data on the health of a large number of patients at a regional level through the use of algorithms (cf. in particular provision of the Guarantor n. 63, 64, 65, 66, 67, 68, 69 and 70 of 24 February 2022, web doc. n. 9752177, 9752221, 9752260, 9752299, 9752410, 9752433, 9752490 and 9752524).

Given all of the above, it has been ascertained that the Company has processed personal data, including those relating to the health of patients of the regional health service, in the absence of a suitable legal prerequisite and therefore in violation of the principles applicable to the processing and of the provisions to articles 5, par. 1, lit. a), 9, of the Regulation, as well as of the art. 2-sexies of the Code.

5.2. Information for interested parties

In its defense briefs, the data controller has not provided clarifications regarding the dispute relating to the violation of the obligation to provide the interested parties with information on the processing of personal data pursuant to articles 13 and 14 of the Regulation.

Given this, given that for the treatments carried out, none of the exemptions from carrying out this information obligation, pursuant to art. 14, par. 5 of the Regulation and that the data were obtained by the Company by accessing its Datawarehouses, the violation of the principle of transparency pursuant to art. 5, par. 1, lit. a) and in art. 14 of the Regulation.

5.3 Impact assessment

The treatments carried out by the Company concerned data relating to the health of a large number of vulnerable subjects. The case in question is in fact one of those for which the controller is required to carry out, "before proceeding with the processing, an assessment of the impact of the processing envisaged on the protection of personal data" (Article 35 of the Regulation). This is because, for the treatment in question, there are certainly two of the criteria indicated by the European Data Protection Committee to identify the cases in which a treatment must be the subject of an impact assessment. In particular, reference is made to the following criteria: processing of "sensitive data or data of a highly personal nature" and of "data relating to vulnerable data subjects" including patients (see Guidelines on impact assessment on data protection and determining whether the processing "may present a high risk" for the purposes of Regulation (EU) 2016/679 adopted on 4 April

2017, as amended and last adopted on 4 October 2017, and endorsed by the European Committee for data protection on 25 May 2018 - WP 248 rev.01, III, letter B, points 4 and 7). It is also believed that, with reference to the present case, the criteria relating to the "processing of data on a large scale" may also be satisfied considering that, according to what is declared in the documents, the processing concerned over 9,000 data subjects and the innovative use of new technological or organizational solutions (see the aforementioned Guidelines, III, letter B, points 5 and 8).

It should also be noted that the emergency provisions adopted over the last few months provide for emergency interventions which involve the processing of data and which are the result of a delicate balance between public health needs and those relating to the protection of personal data, in accordance to what is dictated by the Regulation for the pursuit of reasons of public interest in the sectors of public health (cf. art. 9, par. 1, letter i)). Of course, it remains understood that the processing of personal data connected to the management of the aforementioned health emergency must take place in compliance with the regulations in force on the protection of personal data and, in particular, with the principles applicable to the treatment, pursuant to articles 5 and 25, par. 2, of the Regulation, partially referred to above.

Given this, it should be noted that the aforementioned emergency legislation has not derogated from the provisions on the protection of personal data relating to the assessment of the impact on data protection (Article 35 of the Regulation), as demonstrated by the numerous interventions of the Authority on the subject . In fact, the Guarantor intervened with reference to the impact assessment with reference to the treatments carried out in an emergency context in relation to the national contact tracing system - Immuni App (see provisions of 1 June 2020, 25 February 2021 and 24 November 2022), to the Covid-19 green certifications (so-called green pass, see opinion of 9 June 2021, web doc. n. 96680064, opinion of 31 August 2021, web doc. n. 9694010, opinion of 11 October 2021, web doc. n 9707431, dated 27 January 2022, web doc. n. 9742129 and dated 18 February 2022, web doc. n. 9746905) and to specific treatments carried out by Healthcare Companies in relation to the emergency from Covid-19 (see provisions of 13 May 2021, web doc. No. 9685332, of 13 January 2022, web doc. No. 9744496).

Therefore, the violation of the obligation pursuant to art. 35 of the Regulation.

6. Conclusions

In the light of the assessments referred to above, taking into account the statements made by the Company during the investigation and considering that, unless the fact constitutes a more serious offence, anyone who, in a proceeding before the

Guarantor, falsely declares or certifies news or circumstances o produces false deeds or documents and is liable pursuant to art. 168 of the Code "False statements to the Guarantor and interruption of the execution of the duties or the exercise of the powers of the Guarantor", the elements provided by the data controller in the defense briefs do not allow to overcome all the findings notified by the Office with the act of initiation of the procedure, since none of the cases provided for by art. 11 of the Regulation of the Guarantor n. 1/2019.

For these reasons, the aforementioned preliminary assessments of the Office are confirmed and the illegality of the processing of personal data carried out by the Western Friuli University Company is noted in violation of the principles of processing pursuant to articles 5, par. 1 lit. a), 9, of the Regulation, as well as of the art. 2-sexies of the Code; in violation of the principle of transparency, not having provided the interested parties with specific information regarding such processing of personal data envisaged by art. 14 of the Regulation; in violation of the owner's obligations regarding the impact assessment on the protection of personal data pursuant to art. 35 of the Regulation.

The violation of the aforementioned provisions also renders the administrative sanction envisaged by art. 83, par. 4 and 5 of the Regulation, pursuant to articles 58, par. 2, lit. i), and 83, par. 3, of the same Regulation.

In this context, given the absence of a suitable legal basis for the processing of the personal data in question and that the ASFO has not provided indications regarding the cancellation of the same, it is deemed necessary to order the aforementioned Company, pursuant to art. 58, par. 2, lit. d), of the Regulation, the deletion of data resulting from the aforementioned processing of information present in the company databases covered by this provision, to be completed within 90 days of the adoption of this provision.

7. Adoption of the injunction order for the application of the pecuniary administrative sanction and accessory sanctions (articles 58, paragraph 2, letter i and 83 of the Regulation; article 166, paragraph 7, of the Code)

The violation of the articles 5 par. 1, lit. a), 9, 14 and 35 of the Regulation as well as articles of the articles 2-sexies and 75 of the Code, caused by the conduct of the Western Friuli University is subject to the application of the administrative fine, pursuant to art. 83, par. 4, lit. a) and 5, lett. a) and b) of the Regulation.

The Guarantor, pursuant to articles 58, par. 2, lit. i) and 83 of the Regulation, as well as art. 166 of the Code, has the power to "impose a pecuniary administrative sanction pursuant to article 83, in addition to the [other] [corrective] measures referred to in this paragraph, or instead of such measures, according to the circumstances of each single case" and, in this context, "the

College [of the Guarantor] adopts the injunction order, with which it also orders the application of the ancillary administrative sanction of its publication, in whole or in part, on the website of the Guarantor pursuant to article 166, paragraph 7, of the Code" (art. 16, paragraph 1, of the Guarantor's Regulation no. 1/2019).

The aforementioned pecuniary administrative sanction 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 the light of the elements provided for in art. 83, par. 2 of the Regulation. In relation to the violation of personal data notified by the data controller, pursuant to art. 33 of the Regulation, it is noted that:

- the conduct involved data relating to the health of over 40,000 patients of the regional health service, of which over 9,000 from the ASFO;
- the treatment took place in the emergency context caused by the covid-19 pandemic;
- the Guarantor has not received any reports or complaints from specific interested parties in relation to the question examined;
- the Company cooperated fully with the Authority during the investigation and in this proceeding;
- despite having been the recipient of another sanction, the same concerns other cases of treatment (health dossier) with reference to which the data controller operates through the same data processor (provision of 26.5.2022, n. 200).

Based on the aforementioned elements, evaluated as a whole, it is decided to determine the amount of the pecuniary sanction provided for by art. 83, par. 4 letter. a) and 5, lett. a) and b) of the Regulation, in the amount of €55,000 (fifty-five thousand) for the violation of articles 5, par. 1 lit. a), 9 and 14 and 35 of the Regulation and 2-sexies of the Code, as a pecuniary administrative sanction withheld, pursuant to art. 83, par. 1 and 3, of the Regulation, effective, proportionate and dissuasive.

It is also believed that the ancillary sanction of publication on the Guarantor's website of this provision should be applied, provided for by art. 166, paragraph 7 of the Code and art. 16 of the Regulation of the Guarantor n. 1/2019, also in consideration of the type of personal data subject to unlawful processing.

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

ALL THIS CONSIDERING THE GUARANTEE

declares the unlawfulness of the processing of personal data carried out by the Western Friuli University, for the violation of the art. 5, par. 1, lit. a), 9, 14 and 35 of the Regulation and of the art. 2-sexies of the Code in the terms set out in the justification.

ORDER

pursuant to articles 58, par. 2, lit. i) and 83 of the Regulation, as well as art. 166 of the Code, to the Western Friuli University Company, Via della Vecchia Ceramica, 1 33170 Pordenone (PN) Tax code/VAT number n. 01772890933, to pay the sum of €55,000 (fifty-five thousand) as an administrative fine for the violations indicated in this provision. 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 fine imposed.

ENJOYS

to the aforementioned Company:

- In case of failure to settle the dispute pursuant to art. 166, paragraph 8, of the Code, to pay the sum of €55,000 (fifty-five thousand) in the manner 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 n. 689/1981;
- pursuant to art. 58, par. 2, lit. d), of the Regulation, to the Giuliano Isontina University Company within 90 days of notification of this provision, to proceed with the cancellation of the data resulting from the processing of the information present in the company databases covered by this provision.
- pursuant to art. 58, par. 1 lit. a) of the Regulation and 157 of the Code, to communicate which initiatives have been undertaken in order to implement the above enjoined with this provision and in any case to provide adequately documented feedback, within 20 days of the expiry of the aforementioned term; any failure to reply may result in the application of the pecuniary administrative sanction provided for by art. 83, paragraph 5, of the Regulation

HAS

pursuant to art. 166, paragraph 7, of the Code, the entire publication of this provision on the website of the Guarantor and believes that the conditions set forth in art. 17 of Regulation no. 1/2019 concerning internal procedures having external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor.

Pursuant to art. 78 of the Regulation, of the articles 152 of the Code and 10 of Legislative Decree no. 150/2011, against this provision it is possible to lodge an 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 appellant resides abroad.

Rome, 15 December 2022

PRESIDENT

Station

THE SPEAKER

guille

THE SECRETARY GENERAL

Matthew

(1) By "initiative medicine" we mean a model of care oriented towards the "active promotion" of the health of the individual, especially if suffering from chronic diseases or disabilities, and towards empowering people in their own treatment path (source: Ministry of Health http://www.salute.gov.it/portale/temi/p2_6.jsp?id=496 &area=Cure%20primarie&menu=cure, see, among many references, Ministry of Health, General Assembly of the Superior Health Council , "Telemedicine - national guidelines", 10 July 2012, see par. 2.3.2, Decree 02 April 2015, n. 70 - Regulation establishing the definition of qualitative, structural, technological and quantitative standards relating to hospital assistance, Agreement between the Government, the Regions and the autonomous Provinces of Trento and Bolzano on the planning guidelines for the use by the Regions of the restricted resources pursuant to article 1, paragraphs 34 and 34 bis, of the law of 23 December 1996, n. 662 for the realization of the priority objectives of national importance for the year 2014.