

INDEX

1. INTRODUCTION	2
2 DEFINITIONS	2
3 THE SUBJECTS	3
3.1 Producer companies - Authentication and authorization system of the person responsible for transmitting data to the Registry.....	3
3.2 Ministry of Health - Authentication and authorization system of the Registry Manager	4
4 REGISTER DATA	4
4.1 Section A - Conventions, disbursements, agreements	4
4.2 Section B - Shares, capital shares, bonds, proceeds.....	7
4.3 Methods of data transmission to the Registry and control tools	9
4.4 Section C - Acts of imposition of sanctions.....	9
5 CONSULTATION OF THE ELECTRONIC PUBLIC REGISTER	10
6 INFRASTRUCTURE CHARACTERISTICS OF THE REGISTER	11
6.1 Management of storage media	11
6.2 Suitable measures to guarantee service continuity	12
6.3 Suitable measures to guarantee data protection	13

1. INTRODUCTION

This technical specification is an integral part of the implementing decree of the provisions referred to in article 5, paragraph 7, of Law no. 31 May 2022. 62, regarding the transparency of relationships between manufacturing companies, entities operating in the health sector and healthcare organizations and regulates the Register and the electronic public register with reference to:

- the subjects who feed it;
- the data subject to transmission and publication;
- consultation methods;
- the infrastructural characteristics.

2 DEFINITIONS

For the purposes of this specification:

- a) Law, Law 31 May 2022, n. 62;
- b) Registry, the information system established at the Ministry of Health which allows the management of data useful for the purposes of the Law;
- c) business register, database of national interest pursuant to article 60 of Legislative Decree no. 7 March 2005. 82 and subsequent amendments;
- d) *impresa in un giorno* (impresainungiorno.gov.it), the national telematic service established by law 133/08 with the aim of facilitating the transmission of information between businesses and the Public Administration. The data controller of personal data is UnionCamere;
- e) NSIS platform, the access portal reserved for the applications of the New Health Information System and the Ministry of Health;
- f) Data Processing Center or CED, the infrastructure dedicated to hosting services of the complex of technological components of the National Health Information System, where logical and organizational physical security services are the subject of specific procedures and processes;
- g) XML, the open, text-based markup language that provides structural and semantic information about the actual data. Acronym for “eXtensible Markup Language” metalanguage created and managed by the World Wide Web Consortium (W3C);
- h) user profile, the set of information, uniquely associated with a person, which allows identifying which data they can access, as well as the processing permitted to them.

3 THE SUBJECTS

The subjects who feed the Register are the following:

- manufacturing companies pursuant to art. 2, c.1, letter. a) of the Law;
- the Ministry of Health.

3.1 Producer companies - Authentication and authorization system of the person responsible for transmitting data to the Registry

The data transmission is carried out by one or more persons delegated by the legal representative of the manufacturing company or, in the case of a manufacturing company based abroad, by its representative in Italy. The methods by which to exercise the delegation are made available on the website of the Ministry of Health.

The legal representative of the manufacturing company, based on his organization, can also delegate multiple natural persons responsible for transmitting data to the Registry, who share all the data under the responsibility of the manufacturing company itself.

In the event that the manufacturing company or, in the case of a manufacturing company based abroad, the representative in Italy is registered in the business register, the delegation and access to the NSIS platform of the person delegated by the legal representative takes place through the digital identity tools and delegation features made available by Impresa in one day. In the case of a manufacturing company based abroad that does not have a company as its representative in Italy, the methods for granting delegation to persons responsible for transmission are published on the website of the Ministry of Health. In the case of a manufacturing company that is not registered in the Chamber of Commerce Register, the access methods are published on the website of the Ministry of Health.

The Ministry of Health has an authentication and authorization system, as well as digital identity management, through which authorization profiles are defined provided for each system, defined according to the logic of role-based access control and broken down in relation to the user's role and functions. The application administrators, appointed by the Ministry of Health, manage the designation of users and the assignment of access privileges.

The person delegated by the manufacturing company is assigned a specific user profile "Responsible for transmitting data to the Registry" on the NSIS platform, limited to the data under the responsibility of the manufacturing company itself.

Users access the services of the Ministry of Health through standard devices (National Services Card, Electronic Identity Card, SPID), defined by current regulations, as tools for telematic authentication of services provided online by public administrations, in compliance with Article 64 of the Digital Administration Code.

3.2 Ministry of Health - Authentication and authorization system of the Registry Manager

The staff of the Ministry of Health office in charge of managing the Registry access the NSIS platform, with the "Register Manager" user profile, using standard device tools (National Services Card, Electronic Identity Card, SPID) or tools multi-factor authentication. This profile allows you to manage supervisory actions and record data relating to sanctions imposed.

4 REGISTER DATA

The Register manages the data necessary to feed the three distinct sections referring respectively to:

a) disbursements, conventions and agreements, referred to in article 3 of the Law (Section A);

b) shares, capital shares, bonds and proceeds deriving from industrial or intellectual property rights, referred to in article 4 of the Law (Section B);

c) acts of imposition of sanctions, referred to in article 6 of the Law (Section C).

4.1 Section A - Conventions, disbursements, agreements

Section A is divided as follows:

- A1 - Data reference period
- A2 - Manufacturing company
- A3.1 - Intermediary (natural person)
- A3.2 - Intermediary (legal person)
- A4 - Conventions, disbursements, agreements
- A5.1 - Counterparty/Beneficiary (natural person)
- A5.2 - Counterparty/Beneficiary (legal person)

Section A - Conventions, disbursements, agreements (art. 3, Law 62/2022)

SECTION	INFORMATION CONTENT	DESCRIPTION	OBJECT OF PUBLICATION IN THE REGISTER
A1 Data reference period	Year and semester of survey	Indication of the year and semester to which the data to be transmitted refers	No
A2 Manufacturing company	Typology	Type of producing company (e.g. economic operator, Third Sector organisation, etc.)	Yes
	Tax code/VAT number	Tax code of the manufacturing company or, in the case of companies based abroad, VAT number	Yes
	Company name/Name	Company name or name of the manufacturing company	Yes
	Registered office	Address of the registered office of the manufacturing company (street, house number, postcode/zip code, municipality, province, country)	Yes
	PEC address/E-mail address	PEC address or, in the case of companies based abroad, email address	No
A3.1 Intermediary (natural person)	First name	Name of the intermediary	Yes
	Surname	Surname of the intermediary	Yes

	Tax ID	Fiscal Code or Tax Identification Number of the intermediary	Yes
	Nation	Country that issued the tax identification number	Yes
	Date of birth	Date of birth of the intermediary	No
	Qualification	Qualification of the intermediary on the basis of which he defined the conditions of the agreement, disbursement or agreement or maintained relationships with the beneficiary	Yes
	Professional domicile	Address of the intermediary's professional domicile (street, house number, postcode/zip code, municipality, province and country)	Yes
A3.2 Intermediary (legal person)	Tax code/VAT number	Tax code or, in the case of intermediaries based abroad, VAT number	Yes
	Business name	Company name of the intermediary	Yes
	Nature of the activity	Nature of the intermediary's activity (e.g. organization of training events, conferences, committees, etc.)	Yes
	Registered office	Address of the intermediary's registered office (street, house number, postcode/zip code, municipality, province and country)	Yes
A4 Conventions, disbursements, agreements	Nature	Nature of the agreement, provision or agreement (e.g. provision of money, goods, services, other utilities or agreement for participation in conferences/training events/committees/commissions, etc.)	Yes
	Cause	Reason for the agreement, provision or agreement	Yes
	Time reference	Start date and end date of the activity (e.g. dd/mm/yyyy - dd/mm/yyyy)	Yes
	Economic value	Remuneration of the agreement, disbursement or agreement with numerical value expressed in	Yes

		euros. To be indicated as zero if no remuneration is foreseen.	
A5.1 Counterparty/Beneficiary (natural person)	First name	Name of the counterparty or beneficiary	Yes
	Surname	Surname of the counterparty or beneficiary	Yes
	Identifier	Tax code of the counterparty or beneficiary	Yes
	Birth place	Place of birth of the counterparty or beneficiary	No
	Date of birth	Date of birth of the counterparty or beneficiary	No
	Qualification	Qualification of the counterparty or beneficiary (e.g. medical director with a complex structure role, fixed-term veterinarian, administrative manager with a simple structure role, healthcare director, etc.)	Yes
	Order registration number	Registration number with the professional association of the counterparty or beneficiary (if applicable)	Yes
Professional domicile	Address of the professional domicile of the counterparty/beneficiary (street, house number, postcode/zip code, municipality, province, country)	Yes	
A5.2 Counterparty/Beneficiary (legal person)	Tax ID code	Tax code of the counterparty or beneficiary	Yes
	Business name	Company name of the counterparty or beneficiary	Yes
	Nature of the activity	Nature of the business of the counterparty or beneficiary	Yes
	Registered office	Address of the registered office of the counterparty/beneficiary (street, house number, postcode/zip code, municipality, province, country)	Yes

4.2 Section B - Shares, capital shares, bonds, proceeds

Section B is divided as follows:

- B1 - Data reference period
- B2 - Manufacturing company

- B3.1 - Owner (natural person)
- B3.2 - Owner (legal person)
- B4 - Shares or capital shares
- B5 - Bonds listed on regulated markets
- B6 - Bonds not listed on regulated markets
- B7 – Income

Section B - Shares and capital shares, bonds, proceeds (art. 4, Law 62/2022)

SECTION B	INFORMATION CONTENT	DESCRIPTION	OBJECT OF PUBLICATION IN THE REGISTER
B1 Data reference period	Year of survey	Indication of the year to which the data to be transmitted refers	No
B2 Manufacturing company established as a company	Typology	Type of producing company (e.g. economic operator, Third Sector organisation, etc.)	No
	Tax code/VAT number	Tax code of the manufacturing company established as a company or, in the case of companies based abroad, VAT number	Yes
	Company name/Name	Company name or name of the producing company established in corporate form	Yes
	Registered office	Address of the registered office of the manufacturing company established as a company (street, house number, postcode/zip code, municipality, province, country)	Yes

	PEC address/E-mail address	PEC address or, in the case of companies based abroad, email address	No
B3.1 Owner (natural person)	First name	Name of the holder	Yes
	Surname	Surname of the owner	Yes
	Identifier	Tax code of the owner	Yes
	Birthplace	Place of birth of the owner	No
	Date of birth	Owner's date of birth	No
	Qualification	Title of the owner (e.g. medical director with a complex structure role, fixed-term veterinarian, administrative manager with a simple structure role, healthcare director, etc.)	Yes
	Professional Domicile	Address of the owner's professional domicile (street, house number, postcode/zip code, municipality, province, country)	Yes
B3.2 Owner (legal person)	Tax ID code	Tax code of the owner	Yes
	Business name	Company name of the owner	Yes
	Nature of the activity	Nature of the owner's business	Yes
	Registered office	Address of the owner's registered office (street, house number, postcode, province, municipality, country)	Yes
B4 Shares or capital shares	Economic value	Numerical value determined pursuant to art. 9, c. 4, letter. a) or b), T.U. 917/19861. (expressed in euros)	Yes
	Qualified participation	Indication whether the overall value of the shares or units constitutes a qualified holding as defined pursuant to art. 67, c. 1, letter. c), T.U. 917/19862.	Yes

B5 Bonds listed on regulated markets	Economic value	Economic value determined pursuant to art. 9, c. 4, letter. a) or b), T.U. 917/1986Error. The bookmark is not defined. (expressed in euros)	Yes
---	----------------	---	-----

1 The normal value is determined: a) for shares, bonds and other securities traded on regulated Italian or foreign markets, based on the arithmetic average of the prices recorded in the last month; b) for other shares, for shares in non-shareholding companies and for securities or participation shares in the capital of entities other than companies, in proportion to the value of the net assets of the company or entity, or, for companies or entities of new constitution, to the total amount of the contributions.

2 [...] The transfer of shares, other than savings shares, and any other participation in the capital or assets of the companies referred to in article 5, excluding the associations referred to in paragraph 3, letter c, constitutes the transfer of qualified shareholdings.), and of the subjects referred to in article 73, paragraph 1, letters a), b) and d), as well as the transfer of rights or securities through which the aforementioned shareholdings can be acquired, if the shares, rights or securities transferred represent, overall, a percentage of voting rights exercisable in the ordinary meeting greater than 2 or 20 percent or a participation in the capital or assets greater than 5 or 25 percent, depending on whether the securities are traded on regulated markets or other equity investments. For the rights or securities through which shareholdings can be acquired, the percentages potentially linked to the aforementioned shareholdings are taken into account. The percentage of voting and participation rights is determined taking into account all transfers made over the course of twelve months, even if to different parties.

SECTION B	CONTENT INFORMATION	DESCRIPTION	OBJECT OF PUBLICATION IN THE REGISTER
B6 Bonds not listed on regulated markets	Date of issue	Bond issue date (dd/mm/yyyy)	Yes
	Nominal value	Overall nominal value of the securities, distinguished for each issue (expressed in euros)	Yes
	Annual yield	Annual yield of securities held, separately for each issue (expressed in euros)	Yes
B7 Annual income	Income from stocks, shares and bonds	Income from shares, capital shares and bonds received by the owner during the year (expressed in euros)	Yes

	Income from industrial or intellectual property rights	Income from industrial or intellectual property rights received by the owner during the year (expressed in euros)	Yes
--	--	---	-----

4.3 Methods of data transmission to the Registry and control tools

The Registry makes available to those responsible for transmission the functions that allow the uploading of data, the control of the outcome of the acquisition, as well as monitoring tools to verify the completeness of the transmitted data. For uploading data, separate record layouts are provided, specific by type of subject and section of the Register, in XML format.

For the details of the coding systems, for the rules governing the record layouts, for the detailed indications regarding the structure of the XML files and the XSD validation schemes to refer to and for the control and verification procedures of the transmitted data, please refer to the functional specifications document and the user manuals published on the website of the Ministry of Health.

4.4 Section C - Acts for the imposition of sanctions

Section C is divided as follows:

- C1 - Recipient of the sanction;
- C2 - Details of the sanction.

Sezione C - Atti di irrogazione delle sanzioni

SECTION C	CONTENT INFORMATION	DESCRIPTION	OBJECT OF PUBLICATION IN THE REGISTER
C1 Recipient of the sanction	Tax code/VAT number	Tax code of the manufacturing company or, in the case of companies based abroad, VAT number	Yes
	Company name/Name	Company name or name of the manufacturing company	Yes
	Date	Date of imposition of the sanction	Yes
C2 Details of the sanction	Object	Object of the act of imposition of the sanction	Yes

	Amount	Amount of the fine (expressed in euros)	Yes
--	--------	--	-----

5 CONSULTATION OF THE ELECTRONIC PUBLIC REGISTER

The electronic public register, which contains exclusively the data subject to publication as indicated in the tables referred to in paragraph 4, is freely accessible for consultation and is divided into sections A, B and C provided for in the art. 2, paragraph 4 of this decree.

The electronic public register is created in accordance with the AgiD Guidelines on the accessibility of IT tools and the Design Guidelines for websites and digital services of the PA, in order to ensure:

- ease of access for the use of services and contents without discrimination;
- simplicity of consultation;
- comprehensibility of the data and homogeneity of their presentation;
- improved viewing across multiple devices through responsive components and mobile-first design.

The electronic public register, pursuant to article 5 paragraph 3 of the Law, makes available functions that allow simple and advanced searches in the three distinct sections of the electronic public register, without prejudice to the adoption of technical measures to comply with the principle of minimization of personal data pursuant to article 5 of Regulation (EU) 2016/679.

The electronic public register also makes available the extraction of the data subject to publication according to open data standards, with the exception of personal data in accordance with the provisions of the art. 52, paragraph 2, of the legislative decree 7 March 2005 n. 82.

The data published in the electronic public register can be reused only under the conditions established by the legislation on the reuse of documents in the public sector, referred to in Legislative Decree 24 January 2006, n. 36. It is understood that, where information relating to natural persons is involved, the reuse of the published data must take place in terms compatible with the original purposes for which the same information was collected by the Ministry of Health and, in particular, in compliance of the principle of purpose limitation referred to in Article 5, paragraph 1, letter b) and Article 6, paragraph 4, of Regulation (EU) 2016/679, with the exclusion of cases in which it is prejudicial to the protection of the privacy and integrity of individuals.

6 INFRASTRUCTURE CHARACTERISTICS OF THE REGISTER

Given the organizational characteristics, the need for information exchange and the characteristics of the data processed, the Ministry of Health Register, based on a standard architecture of the Internet world:

- provides a specific security architecture for the management of personal data processed;
- implements forms of application interoperability between systems.

It is made up, at national level, of:

- a system that hosts the web front-end of the application (acting as a web server);

- a system that hosts the application (having the function of application server);
- a system dedicated to data storage (data server);
- a system dedicated to the authentication of users and messages;
- a system dedicated to data search through simple and advanced query functions.

6.1 Management of storage media

Storage media, which include magnetic tapes, optical discs, and cartridges, can be fixed or removable. To minimize the risk of tampering with information, a storage media custodian role is identified, who is responsible for managing removable storage media.

Storage media manage data based on their type to ensure security and anonymization. The data published on the electronic public register and accessible through the web front-end or the open data standard are managed without the application of restrictions regarding anonymisation. Personal data not subject to publication are managed by applying encryption algorithms and in accordance with Regulation (EU) 2016/679.

In particular, the following measures have been adopted for the management of storage media:

- all media are labeled according to the classification of the data contained;
- an inventory of storage media is kept and subjected to checks according to defined procedures;
- physical protection measures for storage media have been defined and adopted;
- destruction of media no longer used in accordance with the provision of the Guarantor for the Protection of Personal Data regarding WEEE - Waste electrical and electronic equipment and personal data security measures - 13 October 2008 - Official Journal n. 287 of 9 December 2008.

6.2 Suitable measures to guarantee continuity of service

To guarantee the correct operation of the service, procedures have been activated to define times and ways to safeguard the integrity and availability of the data and allow the restoration of the system in the event of events that make it temporarily unusable. These measures are periodically updated on the basis of the evidence that emerges from the analysis of the risks that would derive in particular from the destruction and loss of data. Below are the measures adopted.

- Business Continuity and Disaster Recovery strategies.
- Procedures for periodic data saving (both incremental and historical backup).
- Procedures governing the replacement, reuse and rotation of media at each backup cycle.
- Procedures for Data Recovery.
- Procedures for verifying the effectiveness of both the backup and the possible subsequent recovery.
- Software updated according to the timing established by the manufacturers or, periodically, following maintenance interventions.

- Databases configured to allow complete recovery of information without causing loss of integrity and availability.
- Uninterruptible power supplies which, in the event of a power failure, guarantee operational continuity.

These measures are applied to guarantee continuity of service in the following time slots:

- From Monday to Friday: from 07.30 to 21.00
- Saturday: from 07.30 to 15.00

Business Continuity, Disaster Recovery and Data Recovery interventions are designed to primarily guarantee data acquisition and storage functions, to guarantee to manufacturing companies, as defined by this decree, the execution of the obligation established by the Law.

The Ministry of Health also adopts technical-organizational measures aimed at ensuring 24/7 continuity of the provision of content and data to the public of its institutional website and related thematic sites. This perimeter includes “Transparent healthcare”.

6.3 Suitable measures to guarantee data protection

To guarantee the protection of the register data, physical and logical security measures have been activated to safeguard the integrity of the information. These measures are periodically updated on the basis of the evidence that emerges from the analysis of the risks deriving in particular from the accidental or illegal modification of the data and include:

- logical isolation of the network;
- protection of data and applications from damage caused by computer viruses;
- user authentication;
- control of access to applications and data;
- integrity of the messages exchanged;
- encryption of the personal data of those responsible for transmission and for data that cannot be consulted through the web front-end and the open data standard.

All systems hosted at the Data Processing Center (CED) are connected to a local network and connected to the communication infrastructures through appropriately configured firewall and proxy services. Furthermore, the security of the systems themselves is increased through:

- IPS/IDS (Intrusion Prevention System/Intrusion Detection System) tools placed at network access points in order to allow the identification of hostile activities, hindering access by unidentified subjects and allowing an automatic reaction to intrusions;
- an access management and user profiling system, which provides, where appropriate, strong authentication tools;

- a system for recording user access operations to the systems and processing operations (either through application functions or direct access), in order to allow the identification of any anomalies;
- a Log Management and Correlation service (SIEM) which carries out logging, monitoring and correlation activities of security events;
- an Antivirus and Host IPS management service which centralizes the management of antivirus and HIPS (Host Intrusion Prevention System) components in order to prevent illicit intrusions and combat threats linked to malicious software;
- software updates, according to the timing established by the manufacturers, or, periodically, following maintenance interventions;
- database configurations to allow complete restoration of information without causing loss of integrity and availability;
- solutions for business continuity;
- use of a control tool for system administrator access;
- use of a tool for controlling the management of access privileges by database administrators;
- use of the HTTPS channel with TLS V1.2 or higher protocol.

With regard to the system for recording operations carried out on the system, for the purposes of verifying the lawfulness of data processing:

- the logs are protected with suitable measures against any improper use;
- the logs are kept for 12 months and deleted upon expiry.