

Italy Adopts New Transparency Rules for Health Care Providers (*Sunshine Act*)

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On June 26, 2022, Law No. 62 of May 31, 2022, concerning “*Provisions on transparency of relations between manufacturing companies, health care providers and health care organizations*” (the “Law”) came into force.

The Law promotes the transparency of public interest data regarding financial transactions and interest relationships between companies and health care entities.

The objective of the new regulations is to prevent and counter corruption and improper administrative actions. Companies that produce drugs, instruments, equipment, goods and services (including non-medical ones) and entities operating in the health sector, including medical organizations, now have to declare all relationships “*having economic significance or advantage*” between them. To this end, a public electronic register open for consultation to the public, called “*Transparent Healthcare*” (“*Sanità trasparente*”), will be created on the website of the Italian Ministry of Health (the “Ministry”).

If you have any questions concerning this alert memorandum, please reach out to your regular firm contact or the following authors.

MILAN

Roberto Bonsignore
rbonsignore@cgsh.com

Giulia Checcacci
gcheccacci@cgsh.com

MILAN
Via San Paolo 7
20121 Milan, Italy
T: +39 02 72 60 81

ROME

Mario Siragusa
msiragusa@cgsh.com

Marco D'Ostuni
mdostuni@cgsh.com

Cesare Rizza
crizza@cgsh.com

ROME
Piazza di Spagna 15
00187 Rome, Italy
T: +39 06 69 52 21



1. The Law

The Law draws from similar U.S. legislation adopted in 2010, the *Physician Payments Sunshine Act*, a name also used in the rest of the world to refer to such regulations. Similar legislation can be found, in particular, in the jurisdictions of other EU countries, such as France, Denmark, Belgium, Greece, Latvia, Portugal, Romania and Slovakia, as well as in the UK.

The rationale behind this legislation is to empower health care professionals in their relationships with the industry and to increase public awareness of the financial ties between pharmaceutical companies and professionals¹.

2. The affected operators

The Law identifies three categories of entities affected by the new legislation regarding the reporting requirements²:

- i) companies active in the field of human and veterinary health, *i.e.* any entity that carries on an activity aimed at the production or marketing of drugs, instruments, equipment, goods or services that can be marketed in that field;
- ii) entities active in the health sector who are responsible for the management and allocation of resources or who participate in decision-making processes regarding drugs, devices, technologies and other goods; and
- iii) health care organizations (such as health care companies, hospitals and inpatient

or nursing institutions).

3. Disclosure requirements

The Law requires companies that are active in the production or marketing of products or services in the field of human and veterinary health to report the following relationships to the Ministry, for publication in the electronic register:

- conventions and disbursements of money, goods, services or other benefits made by a manufacturing company to either (a) a health care entity, when they have a unit value above €100 or total annual value greater than €1,000; or (b) a health care organization, when they have a unit value above €1,000 or total annual value greater than €2,500³;
- agreements between manufacturing companies and health care entities or health care organizations that produce direct or indirect benefits⁴.

In addition, Article 4 of the Law envisages that manufacturing companies set up under a corporate form must report to the Ministry – by January 31 of each year – the identification data of health care entities and health care organizations for which one of the following conditions applies:

- i. holds shares or units of the company's capital or holds bonds issued by that company;
- ii. has received fees from the company in the previous year for licensing the economic use of industrial or intellectual property rights⁵.

¹ See Article 1(2) of the Law.

² See Article 2(1) of the Law.

³ See Article 3(1) of the Law. In the cases provided for in Article 3, the manufacturing company shall electronically transmit data identifying the grantee of the disbursement or the counterparty to the agreement or arrangement, as well as data on the disbursement, agreement or arrangement itself, including the date, nature and amount.

⁴ See Article 3(2) of the Law. The notion of “benefits” includes participation in conferences, training events, advisory bodies or scientific committees, and the establishment of research, consulting or teaching relationships.

⁵ In the cases provided for in Article 4 of the Law, a digital report must be submitted to the Ministry, indicating – among other things – the value of shares, capital shares or bonds listed or not listed on regulated markets; income

4. The “*Transparent Health Care*” registry

One of the main innovations of the Law is the establishment of an online public registry called “*Transparent Healthcare*” within the Ministry’s institutional website.

The registry will be freely accessible to anyone interested and will be equipped with search and retrieval functions for notices, data and any sanctions imposed. Notices will be searchable for five years from the date of publication, after which they will be deleted.

5. Penalties for failure to report

The Ministry exercises supervisory functions over the implementation of the Law, and may impose administrative fines in the amount of (i) between €1,000 and €50,000, in the case of failure to report; (ii) between €5,000 and €50,000, in the case of providing incomplete data; and (iii) unless the act constitutes a crime, between €5,000 and €100,000, in the case of a manufacturing company providing false data⁶.

Finally, to make enforcement of the Law more effective, a whistleblowing channel was established to report to the Ministry any violations of the obligations under Articles 3 and 4.

6. Conclusions

The new provisions are inspired by the principles of transparency and the prevention of conflicts of interest already outlined in the guidelines of the main trade associations, such as Farindustria⁷. The new obligations under the Law may indeed be integrated into any policies and procedures already adopted by entities operating in the health sector (*e.g.*, in the organization, management and control model

adopted pursuant to Legislative Decree No. 231/2001 and/or in anti-corruption procedures).

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from shares, capital shares and bonds received by the holder in that year; and income from industrial or intellectual property rights received by the holder in that year.

⁶ See Article 6 of the Law.

⁷ V. Farindustria, Code of Ethics, updated April 5, 2022, § 5 (“*transparency of value transfers between pharmaceutical industries, health care providers and health care organizations*”), available at: <https://www.farindustria.it/app/uploads/2018/06/2022-APRILE-5.pdf> (in Italian).