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# Healthcare: Medical Devices 2023

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**Italy: Trends and Developments**

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Studio Legale Rinaldi e Associati – RASS

# Trends and Developments

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**Studio Legale Rinaldi e Associati – RASS** was established in Milan in 1995 and now has offices in Rome, Bologna, and Florence. RASS provides legal advice and assistance to foreign corporations interested in operating in Italy, with the objective to guide them in setting up and running their business on the Italian territory, and to Italian companies interested in expanding their activities abroad. RASS covers the following areas of practice: litigation; national and international arbitration; insurance, reinsurance, and related legal and regulatory issues; specific expertise in insurance claims concerning product and dangerous activity liability, professional indemnity, and medical malpractice; directors' and officers' liability; contractor liability; IP, IT, and corporate law; and M&A. The firm's health law team, consisting of two partners and six lawyers, handle a broad range of matters for clients in the healthcare and life sciences sectors, including development and regulatory approval, marketing and distribution, product reimbursement, fraud, abuse, product liability, and intellectual property litigation. RASS also has experience in litigation regarding orthopaedic and trauma surgery.

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## New Rules for Medical and In Vitro Diagnostic Devices in Italy

On 28 September 2022, Legislative Decrees No 137 and No 138 (jointly "Legislative Decrees") entered into force, with the purpose of conforming the Italian regulatory framework to the provisions issued by the EU legislator on medical devices and in vitro diagnostic devices: namely, Regulation (EU) 2017/745, concerning the rules for "the placing on the market, making available on the market, or putting into service of medical devices for human use and accessories for such devices in the Union" (MDR), and Regulation (EU) 2017/746, concerning "the placing on the market, making available on the market, or putting into service of in vitro diagnostic medical devices for human use and accessories for such devices in the Union" (IVDR) (jointly "EU Regulations").

The category of "medical devices" (eg, prostheses, heart valves, and syringes) includes several kinds of products, classified into four risk classes (the lowest risk devices are in the first class while the highest are in the fourth class). "In vitro diagnostic medical devices", on the contrary, include only devices for analyses on samples taken from the human body (blood, urine, and saliva) used both in laboratories and at home, as in the case of self-tests, which the patient uses without intervention of health professionals (one example is the COVID-19 test).

Although efforts to update European legislation on medical devices (and in vitro diagnostic medical devices) started well before the COVID-19 (SARS-CoV-2) pandemic, it is undeniable that the pandemic emphasised the need to ensure greater attention to the health of citizens.

Previous legislation in this field was based on three directives:

- Directive 90/385/EEC, on safe active implantable medical devices;
- Directive 93/42/EEC, on medical devices; and
- Directive 98/79/EC, on in vitro diagnostic medical devices.

These Directives were aimed at achieving a minimum level of harmonisation between the EU member states, without regulating devices in detail. The main purposes of the said Directives were the free trading of medical devices and the removal of technical barriers within the EU, while the efficiency and safety of devices, although pursued and promoted, were both put on the back seat.

On the other hand, the current legal framework focuses on the efficiency of devices and the health of the patients. To pursue these objectives, the EU Regulations require each member state to designate the competent authority for the implementation of the same EU Regulations, which, in Italy, is the Ministry of Health.

Since the beginning of the year 2023, the said Ministry has issued several Decrees to implement the prescriptions contained in the EU Regulations and the Legislative Decrees.

These Decrees deal with various issues, including advertising of medical devices and in vitro diagnostic medical devices, reporting of complaints concerning medical devices and in vitro diagnostic medical devices, and clinical investigations on medical devices.

### *Medical devices advertising*

On 18 March 2023, two decrees (Ref No 23A01664 and 23A01665) of the Ministry of Health (jointly "ADS Rules"), providing new rules on advertising of medical devices, were pub-

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lished in the Italian official gazette and entered into force the day after their publication.

Under Article 26 of Legislative Decree No 137/2022 and Article 22 of Legislative Decree No 138/2022, certain advertisements (such as those regarding products for which medical prescription is required) are prohibited while others are submitted to authorisation by the Ministry of Health, which may establish exceptions by "identification of cases of advertising of medical devices that do not require ministerial approval" and "identification of cases of advertising of in vitro diagnostic medical devices that do not require ministerial approval".

The first decree of the ADS Rules, implementing Article 26, paragraph 6 of Legislative Decree No 137/2022, has excluded from ministerial approval advertisements for condoms and accessories of medical devices if the information contained therein exclusively refers to non-health properties.

Similarly, the second decree of the ADS Rules, implementing Article 22, paragraph 6 of Legislative Decree No 138/2022, has exempted from authorisation of the Ministry advertisements relating to accessories for in vitro diagnostic medical devices provided that they refer to non-health properties.

The ADS Rules have exempted from prior approval:

- advertising carried out by manufacturers or distributors, referring to their name or the field of their activity, provided that no specific characteristic of the devices is mentioned;
- promotion of medical devices by offering for sale multiple packs at the same price as one pack or by using various methods of promotional contests or premiums, provided that properties and characteristics of the medical device are not advertised;
- publication of images or graphical representations of a device on sales price lists and advertisements of any discounts offered to the public; and
- publication of images of the device or its packaging and its description in case of "distance selling", within the meaning of Article 6 of Regulation (EU) 2017/745, provided that the full version of the instructions for use is given and accessible.

In any case, whenever an advertisement contains information which may cause a risk to consumer health, the Ministry of Health shall order:

- its immediate suspension; and/or
- the issue of a notice rectifying and clarifying the information provided to the general public.

The ADS Rules are supplemented by the new Guidelines (issued by the Ministry of Health on 21 July 2023) for non-prescription and over the counter medicines as well as for web and social media advertising. Such Guidelines prescribe specific wording/warning and provide for specific rules to be met to fulfill the requirements of Legislative Decree No 219/2006.

### *Terms and conditions for reporting complaints*

Reporting of complaints involving medical devices and in vitro diagnostic medical devices is now governed by two different decrees of the Ministry of Health, both issued on the Decree of 26 January 2023, one "for reporting complaints involving medical devices by healthcare professionals, lay users, and patients", published in the official gazette on 31 March 2023, and the

other "for reporting complaints involving in vitro diagnostic medical devices by healthcare professionals, lay users, and patients", published in the official gazette on 25 May 2023.

The two above decrees, consisting of four articles each and containing almost the same wording, give a definition of "lay person" (lay user), ie, a person who, according to Article 2, paragraph 1, point 38 of Regulation (EU) 2017/745 and Article 2, paragraph 1, point 31 of Regulation (EU) 2017/746, "does not have formal education in a relevant field of healthcare or medical discipline".

Lay users and patients are entitled to make complaints regarding medical devices and/or in vitro diagnostic medical devices by means of health centres, pharmacies, doctors, or paediatricians.

Healthcare professionals to whom complaints are reported from lay users and patients shall send these reports to the Ministry of Health within 30 days. Reports must first be sent to the manufacturer and online to the Ministry of Health according to the terms indicated on the relevant website.

The Ministry of Health has also published the "Guidelines for Reporting Complaints on Medical Devices and In Vitro Diagnostic Medical Devices" ("Guidelines") by means of a memorandum dated 6 June 2023, aimed at providing clarifications and instructions to handle complaints in a unified and harmonised manner throughout the national territory. The Guidelines provide, on the one hand, the definition of "complaint", underlining the difference between complaints and incidents, and, on the other hand, a non-exhaustive list of events that can be classified as complaints or incidents.

The Guidelines clarify that the definition of "complaint" (contained in the Legislative Decrees) is set out in technical standard EN ISO 13485:2016, referring to it as "written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety, or performance of a medical device that has been released from the organisation's control or related to a service that affects the performance of such medical devices".

Secondly, according to the Guidelines, any event involving a device placed on the market can be classified as a complaint, incident, or serious incident.

A different definition of "incident" is set out in the EU Regulations. While, under Regulation (EU) 2017/745, it amounts to "any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect", under Regulation (EU) 2017/745, the incident consists of "any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any harm as a consequence of a medical decision, action taken or not taken on the basis of information, or result(s) provided by the device".

To determine whether the reported adverse effects amounts to a complaint or an incident, the guidelines state that the health professional should assess whether it concerns:

- a malfunction and/or alteration of the device's characteristics and/or performance;

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- an inaccuracy in the information provided by the manufacturer;
- an error in use determined by ergonomic characteristics;
- an undesirable medical device adverse reaction; or
- an injury resulting from the medical decision, action, or omission based on the information or results provided by the device for in vitro diagnostic medical devices.

If the event falls into at least one of the above cases, it should be qualified as an incident.

In any event, the guidelines suggest that, even when it is excluded that an incident has been reported, the involvement of the patient/user should always be investigated.

In general, complaints do not involve patients/users and are related to events occurring before the device was used.

Where the event generating the complaint has involved patients/users or third parties, it is always necessary to verify their health conditions. If the health conditions have been affected by the event to which the complaint relates, it is always appropriate to consider the complaint as an incident.

### *Clinical investigations*

On 13 June 2023, two further decrees ("CI Decrees") were published in the official gazette setting out the terms for:

- submitting applications for clinical investigations for devices that are not CE marked or are CE marked but used outside their intended purpose; and
- notifying clinical investigations on CE marked devices used within their intended use.

The CI Decrees, entered into force on 13 July 2023, implement the principles set forth in paragraphs 2 and 3 of Article 16 of Legislative Decree No 137/2022 and are intended to conform Italian legislation to Regulation (EU) 2017/745.

The CI Decrees:

- identify the entities entitled to submit applications and send notifications concerning clinical investigations;
- clarify the terms for submitting clinical investigation applications and communications;
- define how and when to obtain a nationally valid opinion from an ethics committee; and
- define the terms for notifying with regard to the beginning of investigations.

As a general rule, the sponsors of clinical investigations on medical devices (or the person representing them, duly authorised by the sponsors in the form provided for by law) shall address the relevant communications to the Ministry of Health, the competent authority for Italy.

The CI Decrees establish that clinical investigations requiring patients to be submitted to additional, invasive, or burdensome procedures (compared to those performed under normal conditions of use of a CE marked device) need to obtain the opinion of the nationally valid ethics committee (in this case, a favourable opinion issued by a territorial ethics committee is not sufficient) within 30 days of the date of notification of the clinical investigation.

Furthermore, two decrees (Ref No 23A03363 and 23A03364) were published by the Ministry of Health on 14 June 2023 to deal with:

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- independence, transparency, and impartiality of the entities in charge of processing clinical investigation applications; and
- the requirements of healthcare facilities eligible to carry out clinical investigations conducted to demonstrate the conformity of medical devices.

The first decree, implementing paragraphs 5 and 8 of Article 16 of Legislative Decree No 137/2022, is intended to establish the rules for preventing conflicts of interest and undue influence on the people (hereinafter, "experts") in charge of assessing and validating applications for clinical investigation and related documentation concerning CE marked devices and non-CE marked devices.

In particular, the experts, identified by the Ministry of Health pursuant to Article 70 of Regulation (EU) 2017/745, must not be subject to any influence that may alter their judgement, and must carry out their activities in an independent, transparent, and impartial way. They must not find themselves in a conflict of interest or be subject to undue influence by sponsors, economic operators, investigators, or any other party involved in the conduct, management, or financing of clinical investigations under evaluation and validation.

On an annual basis, the experts have to submit a declaration stating their financial interests and any link with persons in respect of whom conflicts of interest may arise. This declaration, to be drawn up according to the model available on the website of the Ministry of Health, shall be taken into account when assigning evaluation and validation of each clinical investigation.

The experts are also required to refrain from taking part in discussions relating to clinical investigations if they find themselves in situations of conflict of interest, even if potential, or are subject to undue influence.

Furthermore, in order to ensure that the assessment of applications for investigations is carried out jointly by an appropriate number of people with the necessary qualifications and experience, it has been established that experts with proven scientific and professional qualifications shall be selected among the employees of bodies carrying out research, healthcare, or university training activities. The Ministry of Health may also identify experts from special lists drawn up according to criteria and procedures published on its website.

The second decree, on one hand, details the rules for the suitability of healthcare facilities for carrying out investigations, by making reference to the declarations to be submitted by the legal representatives of such facilities, and, on the other hand, establishes the conditions for permitting the remote testing of devices that can be used through the use of digital technologies.

In particular, this second decree provides that, where the clinical investigation requires activities to be performed with digital devices outside the facility where the investigation is conducted, the operator shall ensure the adoption of appropriate levels of quality and safety and shall implement mechanisms for reporting and managing any adverse events that may occur outside the facility.

### *Reprocessing of medical devices*

Reprocessing is a process performed on a used device to enable its safe reuse. Specifically, with regard to medical devices, Regulation (EU) 2017/745 defines "reprocessing" as "a process carried out on a used device in order to allow

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its safe reuse including cleaning, disinfection, sterilisation, and related procedures, as well as testing and restoring the technical and functional safety of the used device".

Reprocessing, aiming at the subsequent reuse of the device, should be strongly encouraged, since this would allow:

- lower resources consumption, from the perspective of environmental protection;
- lower pollution and a reduction of the costs related to the disposal of each device; and
- a considerable cost reduction for each national health system.

Article 17 of Regulation (EU) 2017/745 leaves it up to the member states to decide whether or not reprocessing and reuse of devices is permitted under the national laws, requiring that a certain safety standard is guaranteed. As a general rule, according to the second paragraph of Article 17, the natural or legal person reprocessing a single-use device "shall be considered the manufacturer of the reprocessed device" and "assume the same obligations imposed on manufacturers under the same Regulation".

Neither Legislative Decree No 137/2022 nor any previous piece of legislation has governed reprocessing in Italy, so it should be inferred that, at the moment, neither reprocessing nor reuse of medical devices are permitted in Italy at present.

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