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INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

New rules on clinical trials

On 6 March, Law 9/2026 was published in the Official Gazette, establishing new rules applicable to clinical trials of medicinal products for human use and implementing Regulation (EU) 536/2014 in Portugal.

Main changes

- **INFARMED**, the Portuguese National Authority for Medicines and Healthcare Products, has been designated as the national contact point and the body responsible for implementing the Regulation. It will be responsible for deciding on applications for authorisation of clinical trials and carrying out supervision.

- The **Ethics Committee for Clinical Research** (*Comissão de Ética para a Investigação Clínica* - "**CEIC**") is the reference ethics committee for the purposes of the Regulation, responsible for assessing ethical issues.

INFARMED has been designated as the national contact point and the body responsible for implementing the Regulation, deciding on applications for authorisation of clinical trials and carrying out supervision.

- Applications for authorisation of clinical trials must be submitted via the website of the European Union provided for in Article 80 of the Regulation.

- After consulting the CEIC, INFARMED validates the application's compliance and verifies whether the trial falls within the Regulation's scope and if the dossier is complete.

- INFARMED's decisions regarding applications for authorisation of clinical trials may be challenged by appealing to the government member responsible for health or through the courts.

Protection of participants

- Mandatory informed consent is required from legal representatives for incapacitated persons/ minors. Minors aged 16 or over who have the capacity to understand must also give consent.

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Investigational medicinal products, medical devices, and tests that exceed standard clinical practice are provided free of charge by the sponsor.

- An exception is made in clinical emergencies, where inclusion without prior consent is permissible if the research relates to the clinical condition, cannot take place outside the emergency context, has prior ethical approval, and offers the prospect of direct benefit.
- As for minors, participation requires the informed consent of the legally authorised representative and the consent of the minor aged 16 or over.
- With regard to adults who are incapable of giving informed consent and who have neither given nor refused their consent prior to becoming incapable, the clinical trial may only be conducted under the terms and conditions set out in Article 31 of the Regulation. This article establishes all the conditions to be observed. Subjects in institutional care may not participate, unless there is a justified exception.

Liability and costs

- **Mandatory insurance:** the sponsor must take out compulsory civil liability insurance to cover both pecuniary and non-pecuniary damage. The sponsor and researcher are jointly and severally liable.
- **Free of charge:** investigational medicinal products, medical devices, and tests that exceed standard clinical practice are provided free of charge by the sponsor (even after the trial, if necessary for continuation of treatment).

Inspection, administrative offences and penalties

Inspection is the responsibility of INFARMED, IP and covers all establishments where the trial takes place, as well as the sites of manufacture and import of investigational medicinal products and the sponsor's premises.

- Fines for non-compliance: €500 to €50,000 (individuals) or €5,000 to €750,000 (legal entities).
- Additional penalties include the suspension or prohibition of clinical trials for up to two years.

Entry into force

- The law will enter into force on 5 April 2026 (30 days after publication). ■