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Provision of Medicinal Products and Medical Devices to Clinical Trial Participants

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FOn 23 October, Ministerial Order No. 465/2026/1 was published, establishing the terms and conditions for the free provision of medicinal products and medical devices to clinical trial participants following the end of their participation, pursuant to Article 14 of Law No. 9/2026, of 6 March, which regulates clinical trials of medicinal products for human use.

Under the newly published Order, the clinical trial sponsor remains responsible for ensuring the free provision of the investigational medicinal products and the medical devices required for their administration, provided that the following conditions are cumulatively met:

- The investigator considers the continued use of the medicinal product by the participant to be essential;
- No alternative treatments with comparable efficacy and safety are available.

As a general rule, this obligation remains in place until the medicinal product is effectively placed on the market and access to it is ensured within National Health Service institutions.

The sponsor's obligation to provide the medicinal product or medical device ceases where an application for public funding of the medicinal product has been submitted and one of the following circumstances applies:

- The application for public funding has been approved; or
- The statutory deadline for a decision has expired without a decision being issued, and the supply of the medicinal product has been authorised under the Exceptional Access Scheme, provided that such authorisation covers the participant.

The obligation to provide the medicinal product free of charge remains in force where the sponsor fails to submit an application for public funding or where such application is rejected. If the application is rejected after exceptional supply has been authorised, the obligation is reinstated.

The conditions governing the continuation of treatment must be set out in the clinical trial protocol and, where applicable, defined before the end of the participant's involvement in the trial, in coordination between the sponsor, the investigator and the trial site. The decision must be based on an individualised and duly substantiated clinical assessment by the investigator. Appropriate clinical follow-up, safety monitoring and the transition to the subsequent access arrangements must also be ensured.

Any exceptional circumstances that may compromise the continuity of treatment must be duly justified and submitted for assessment by the Clinical Research Ethics Committee (CEIC) and INFARMED, I.P.

Thinking about tomorrow? Let's talk today.



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