

New Regulations for PDPs and PDIL

After a long hiatus and public consultations, on June 21, 2024, the Ministry of Health (MS) published Ordinances MS 4.472/24 and MS 4.473/24, which regulate the Productive Development Partnerships (PDPs) and the Local Innovation Development Program (PDIL), respectively.

The PDPs continue to encourage cooperation between public and private institutions, for the development, transfer and absorption of technology, productive and technological training, with the aim of fostering the local production of strategic technologies and products to meet the demands of the Unified Health System (SUS).

The PDPs must be aimed at productive and technological solutions listed by the SUS in the Matrix of Productive and Technological Challenges in Health, as well as meeting the other requirements set out in Ordinance MS 4.472/24. The new regulation also sets out the criteria for evaluating and classifying PDPs, with a strong focus on reducing the time it takes for public laboratories to absorb technologies.

Ordinance MS 4.473/24 deals with the PDIL, the purpose of which is to promote the development of local production and innovation focused on health challenges. According to this legal text, the PDIL can be implemented by promoting local innovation projects, through agreements, terms of decentralized execution (TED), technological orders (a term not defined in the regulation), technological compensation agreements and other related instruments.

Finally, it is important to note that the new regulation has rules applicable to partnerships already in force. In relation to PDPs, Ordinance 4.472/2024 establishes that existing partnerships will be governed by it, respecting the agreements signed and the obligations between the parties. As for the PDIL rules, they stipulate that existing strategic health alliances may be adapted to the PDIL model within twelve months of the regulation coming into force (i.e. until June 21, 2025).

The Campos Thomaz Advogados team is attentive to new legislation and keeps its clients informed of any projects involving technology, innovation and their regulation.