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PUBLIC HEALTH INSTITUTE PUBLISHES TECHNICAL GUIDELINE ON ADVANCED THERAPIES

On March 6, 2026, the Chilean Public Health Institute (ISP) published on its website Technical Guideline No. 257 on Advanced Therapy Medicinal Products (ATMPs), approved by Exempt Decree No. 11/2026 of the Ministry of Health, whose publication in the Official Gazette is still pending.

The guideline represents a regulatory milestone for the life sciences sector in Chile, as it establishes for the first time a specific technical framework for gene therapies, somatic cell therapies, tissue engineering and combined advanced therapy medicinal products. In doing so, it complements Supreme Decree No. 3/2010, by operationalizing criteria related to quality, biosafety, manufacturing and control applicable to these therapies.

The new regulation applies to all activities involving cells or tissues of human origin intended for the development of advanced therapy medicinal products for use in humans.

However, the following cases are excluded from its scope:

- Autologous or allogeneic grafts performed within the same surgical procedure without substantial manipulation.
- Reproductive use of human germline cells.
- Blood and blood products.
- Conventional hematopoietic stem cell transplants.
- Organ or tissue transplants.
- Procedures involving cells or tissues without the intention to formulate an advanced therapy medicinal product.

The guideline was developed considering standards from high-level regulatory agencies, including EMA, PMDA, ANVISA and AEMPS, with the aim of aligning Chile's regulatory framework with international standards for these products.

In particular, the ISP will classify ATMPs according to their sanitary

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risk level, taking as reference criteria used by the EMA and other equivalent regulatory agencies, which will guide evaluation, control, surveillance and enforcement activities.

The Technical Guideline addresses several aspects related to the development and authorization of these products, including quality, provisional use, marketing authorization, manufacturing facilities, quality control and Good Manufacturing Practices (GMP). Among its most relevant aspects are the following:

Quality

• ATMPs must be fully characterized and controlled, and all processes must be validated.
• Strict compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) is required.
• Batch control is mandatory, except in justified cases involving high unit cost and low turnover.
• The ISP may authorize early release in clinical scenarios where time is critical.
• The robustness of the quality assurance system must be documented and demonstrated.

Provisional use

• Any request for provisional use of an ATMP must include a review of the product's quality certification, regardless of the grounds invoked.

Manufacturing

• The guideline establishes specific requirements regarding personnel and facilities, including the appointment of a biosafety officer and the differentiation between manufacturing staff and bioterium personnel.
• It also distinguishes requirements depending on the type of production:

Industrial manufacturing

• Requires highly specialized facilities.
• Requires strict physical segregation and full compliance with GMP specific to ATMPs.

Production for clinical research (Phases I and II)

• Certain infrastructure requirements may be relaxed, provided that risk assessments and adequate controls are implemented.
• Quality control may be outsourced to laboratories authorized by the ISP.

Non-industrial manufacturing (hospital, clinical or academic)

• Allows manufacturing in hospital or academic environments for personalized treatments or treatments intended for a limited group of patients.
• Quality control may be outsourced to ISP-authorized laboratories or to clinical laboratories within the same facility that demonstrate sufficient capability.
• Products may only be distributed within the same healthcare facility where they will be used.

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