
To the Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

Re: Consultation Papers

- 1) ANMAT-MED-BIO 008-00: Advanced Therapies Table
- 2) ANMAT-MED-BIO 007-00: Good Manufacture Practice for Biologics
- 3) ANMAT-MED-BIO 006-00: Establish the requirements, requirements and classification for the production, registration in the REM, authorization and surveillance of Advanced Therapy Medicines

Dear Director,

Established in 1992, the International Society for Cellular Therapy (ISCT) is a global society of clinicians, regulators, researchers, technologists and industry partners with a shared vision to translate cellular therapy into safe and effective therapies to improve patients' lives worldwide.

ISCT offers a unique collaborative environment that addresses three key areas of translation: Academia, Regulatory and Commercialization. Through strong relationships with global regulatory agencies, academic institutions and industry partners, ISCT drives the advancement of research into standard of care. ISCT is the global leader focused on pre-clinical and translational aspects of developing cell-based therapeutics, thereby advancing scientific research into innovative treatments for patients.

Comprised of over 1,300 cell therapy experts across five geographic regions and representation from over 50 countries, ISCT members are part of a global community of peers, thought leaders and organizations invested in cell therapy translation.

ISCT is appreciative of the efforts ANMAT has undertaken to provide clarity and certainty in regulating cellular therapy products. ISCT broadly endorses proposals specified in these recent documents and agrees with the efforts of the government to address the issues surrounding cellular therapy.

One point for consideration would be to provide a product definition that includes language which takes into account the biological characteristics of the final cell therapy product. Specifically, if the final cell therapy has different biological characteristics than the starting cells, the cellular therapy product would be more than minimally manipulated.

On behalf of the Legal and Regulatory Affairs (LRA) Committee of the International Society for Cellular Therapy (ISCT) - South & Central America, thank you for your consideration of our comments. We appreciate the opportunity to provide feedback to the Administration.

Sincerely,

Claudio Zurlo, MD
Chair, South & Central America Legal and Regulatory Affairs Committee
www.celltherapysociety.org