Regulation of cell therapies in Brazil

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Office of Blood, Cells, Tissues and Organs
ANVISA
National Cell Therapy Network

Created in 2008

8 Cell Technology Centers

Ministry of Health
Ministry of Science and Technology

Financial Support
National Cell Therapy Network

Integrated network
Promotion of national scientific research
Development and improvement of techniques
Exchange of knowhow
To issue relevant information
National Cell Therapy Network
Resolution n. 09/2011
ANVISA

Standard for the operation of Cell Technology Centers (CTC)
Resolution n. 09/2011
Cell Technology Centers

• Premises, equipment and materials
• Documentation
• Quality requirements and quality control
• Biosafety
• Eligibility of donors and patients
• Collection
• Processing and storage
• Release for use
• Transportation

Good Cell Practices
Resolution n. 09/2011
Cell Technology Centers

• Clinical Trials – Approval by the Ethical Committees

• Therapeutic use – Acknowledgement by the Medical or Dental Federal Councils
Need to establish which advanced therapy products will be subject to pre-market approval by ANVISA

Cooperation with the Committee for Advanced Therapies-CAT and Medical and Dental Federal Councils
Commercialization of human products

- ATMPs: marketing authorization allowed;
- Donation of the starting materials: safeguarded.
ANVISA Regulatory Agenda

Advanced therapies products:

- Cell Therapies
- Tissue Engineering
- Gene therapy
Advanced Therapies Medicinal Products - ATPMs

Advanced Cell Therapies

Tissue engineering

Gene Therapy

Extensive Manipulation - biological characteristics altered

Clinical Trials and Marketing Authorization

In vivo

Ex vivo
ANVISA Regulatory Agenda

• Revision: Resolutions n. 56/2010 and 09/2011- Good Cell Practices;

• Standard for the approval of clinical trials with advanced therapies products in Brazil- Public Consult in 2017;

• Standard for the marketing authorization of advanced therapies products in Brazil
Thank you!
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