Federal Commission for the Protection against Sanitary Risks (COFEPRIS)

“Regulatory Guidance/Perspectives/Issues”

Marco Antonio Llanas, MD.

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Committee of New Molecules:

- Permanent members:
  - Advice of General Salubrity.
  - Commission of Analytical Control and Extension of Cover.
  - Commission of Evidence and Handling of Risks.
  - General Coordination of the National Institutes of Health.
  - Mexican Institute of the Industrial Property.
Committee of New Molecules:

- Federal Commissioner of the Federal Commission for the Protection against Sanitary Risks. **President.**
- Commissioner of Sanitary Authorization. **Technical Secretary.**
- Executive Director of Product Authorization and Establishments. **Auxiliary Secretary.**
- Director of the National Center of Pharmacovigilance. **Auxiliary Secretary.**
- Representatives of the Academic Associations
Committee of New Molecules:

- Non Permanent members:
  - Academies, Universities, Associations, Advice and Schools of diverse disciplines.
  - Directors of:
    - IMSS (Mexican Institute of Social Insurance)
    - ISSSTE (Institute of Social Security and Services of Workers of the State)
    - DIF (National System for Integral Development of Family)
    - SEDENA (Secretariat of the National Defense)
    - GDF (Government of the Federal District)
  - Directors of Hospitals of Sector Health.
Functions:

- Evaluate the expedition, prorogation or revocation of the clinical trials authorization.

Evaluated proceedings:
Type of proceeding:

- Clinical trails: 252
- Amendments: 267
- Inclusion of medical centers: 649
- Closing of medical centers: 105

1273 proceedings (November, 2007 – April, 2008)

Secretaría de Salud COFEPRIS/CMN, 2008
Type of proceeding:

- Diabetes Mellitus
- Reumatoide Arthritis
- AVC
- Psychiatric
- Asthma
- Thrombosis
- HIV
- Ophthalmic
- Treatment of Pain
- VHB
- Others

Secretaría de Salud COFEPRIS/CMN, 2008
Evaluation process for clinical trials:

- Fulfillment of the established in the Regulation of the General Law of Health in matter of Investigation for the Health

- Authorization request COFEPRIS-04-010-A/COFEPRIS-04-010-B

- Corresponding payment
Minimal requirements:

- Article 222 of the General Law of Health
  - Security and effectiveness
- Article 167 of the Regulation of Consumptions for Health
  - Identity and purity
  - Stability
  - Therapeutic effectiveness and security
  - Therapeutic indication and Projects of label
  - Patent (Intellectual Property)
  - Identification of Origin and Certificate of GPM
  - Certificate of free sale of the origin country
Approval time:

• Clinical trials:
  - From 20 to 90 working days
  - Depends the proceeding, phase of study and type of drug or device
  - COFEPRIS can request supplement data only once during the review phase
  - Sponsor can respond in 10 or 20 working days, depending the requirements (administrative or technicians)
Approval time:

- **New Molecules (Sanitary Registry):**
  - 180 working days
  - Depends the type of drug
  - COFEPRIS can request supplement data only once during the review phase
  - Sponsor can respond in 20 or 45 working days, depending the requirements (administrative or technicians)
Definition of New Molecules:

- Drug or Medicine.
  - It does not have registry at world-wide level
  - With registry at world-wide level but not in Mexico
  - Drug combination, that does not exist in the national market
  - Existing drug in the market that it tries to commercialize itself with another therapeutic indication

*Decree in the Official Newspaper of the Federation, January 02, 2008.*
Necessary changes to increase the investigation:

- Continuous update
- Exchange of information with the rest of the world
- Coordinate work meetings
- Propose new pharmacovigilance mechanisms
- Modification and standardization of the regulation laws
- Definition of guidelines for the evaluation of biotechnological
Purpose:

Guarantee the security and clinical effectiveness through fulfillment of phases III and IV in Mexico.
Thank you for your attention

Questions or explanations, please contact to me:

Telephone: (52) 55 50805200 Ext. 1388

Email: ifai.enlace.cas@gmail.com