CLINICAL RESEARCH REGULATION IN MEXICO: UPDATE

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Ex-President and Ex-Normativity Commissioner, AMEIFAC
Ex-President, Research and Technological Development Commission, CANIFARMA
President, Mexican Society of Dermatology

CHANGES IN THE CLINICAL RESEARCH REGULATION

- Law: Articles 100 and 222 bis
- By-Law: changes in planning phase
- NOM: O12, published as a project
- Others: COFEPRIS’ Agreement on Affairs and Services, and General Rules for Foreign Trade
CHANGES IN THE CLINICAL RESEARCH REGULATION

General Health Law (Article 100, paragraph V). Revised on July 14, 2008

May only be done by health professionals in medical institutions acting under supervision of the competent health authorities

Population genome studies must be part of a research project

CHANGES IN THE CLINICAL RESEARCH REGULATION

COFEPRIS' Agreement on Affairs and Services

DOF June 19, 2009

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CHANGES IN THE HEALTH REGULATION
COFEPRIS’ Agreement on Procedures and Services
DOF June 19, 2009

- A biotechnological drug is taken as any substance which has been produced by molecular biotechnology, has a therapeutic, preventive or rehabilitatory effect, is presented as a pharmaceutical product and is identified as such by its pharmacological activities or physical, chemical and biological properties
- Innovative pharmacological drugs = Reference for non-innovative ones (biocomparables)
- Proven quality, safety, and efficacy
CHANGES IN THE HEALTH REGULATION

Article 222-BIS (cont.)

• Pharmacovigilance = Mandatory
• Biocomparables registration = Clinical trials (and in vitro trials, when applicable)
• Evaluation on case-by-case basis, until specific dispositions are defined, by the New Biotechnological Products Deputy Committee
• Labeling = Manufacturer, source of origin, packaging site, importer name, innovative product same INN

CHANGES IN HEALTH REGULATION

Rule 4.3
(In force since May 1st, 2008)

Companies that make definitive importation of samples covered under a protocol of research in humans, approved by the competent authority, …, must specify the following information:

a) Common international denomination, and generic denomination or scientific name of the sample to be imported

b) Authorization number of the protocol, issued by the competent authority

For the purpose of this rule, samples and products included in this processes may not be commercialized or used for promotion purposes
Figure 2. Regulatory Flowchart for Mexico

- Regulatory Documents From Sites, EC, Hospital, Study Staff: 4–6 weeks
- Protocol Submission to Sector Salud (SS): 2–3 weeks
- SS Approval: 2–3 weeks
- Customs release: 1–2 days
- Study Start

<table>
<thead>
<tr>
<th>Country</th>
<th>Population 2005 (millions)</th>
<th>Time From Final Protocol in English to Start of Site Initiation Visit (SV)</th>
<th>Competent Authority Regulating Research</th>
<th>Recent Country-Specific Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algeria</td>
<td>38</td>
<td>5.5 to 6.5</td>
<td>ANMRA</td>
<td>ANMRA may require increased risk assessment and additional documentation.</td>
</tr>
<tr>
<td>Brazil</td>
<td>184</td>
<td>6 to 9</td>
<td>ANMRA</td>
<td>ANMRA requires additional risk assessment.</td>
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<tr>
<td>Chile</td>
<td>15</td>
<td>4.5 to 5.5</td>
<td>EFS</td>
<td>EFS requires additional risk assessment.</td>
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<td>Colombia</td>
<td>45</td>
<td>4.5 to 5.5</td>
<td>IBBA</td>
<td>IBBA requires additional risk assessment.</td>
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<td>Mexico</td>
<td>108</td>
<td>3 to 4</td>
<td>SG</td>
<td>SG requires additional risk assessment.</td>
</tr>
<tr>
<td>Peru</td>
<td>28</td>
<td>4.5 to 5.5</td>
<td>INF</td>
<td>INF requires additional risk assessment.</td>
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</tbody>
</table>

*Note: Times include drug importation, risk assessment, and additional documentation requied by ANMRA, IBBA, or INF, if required.
### Clinical Research in Mexico

<table>
<thead>
<tr>
<th>Description</th>
<th>2008</th>
<th>2009</th>
</tr>
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<tbody>
<tr>
<td>Patients studied in 2008</td>
<td>70,000</td>
<td></td>
</tr>
<tr>
<td>Patients planned for 2009</td>
<td>68,000</td>
<td></td>
</tr>
<tr>
<td>Investment 2008</td>
<td>1'100'000,000</td>
<td></td>
</tr>
<tr>
<td>Budget 2009</td>
<td>1'350'000,000</td>
<td></td>
</tr>
<tr>
<td>Participating institutions</td>
<td>1,150</td>
<td></td>
</tr>
<tr>
<td>Public institutions</td>
<td>920 (80%)</td>
<td></td>
</tr>
<tr>
<td>Private institutions</td>
<td>230 (20%)</td>
<td></td>
</tr>
<tr>
<td>Number of researchers</td>
<td>2,120</td>
<td></td>
</tr>
<tr>
<td>Number of protocols</td>
<td>650</td>
<td></td>
</tr>
</tbody>
</table>


### Studied Patients in Mexico

![Bar chart showing the number of patients studied in Mexico from 2003 to 2009](chart.jpg)

* Estimate

Number of Protocols

* Estimate

Number of Research Centers

* Estimate
### Estimation of Investment in Mexico

**Cost per Patient (in Mx pesos, not updated)**

* Estimate


![Graph showing investment in Mexico from 2003 to 2009.](image1)


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**Floor Plan Information**

* Estimate

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**Graph showing floor plan utilization.**


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**Details of the construction project.**

* Estimate

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**Analysis of project costs.**

ADDED VALUE

- ADDED VALUE = (MANAGERIAL AND ADMINISTRATIVE) CAPITAL GAIN

- EFFICIENCY (EFFICACY + SAFETY + RATIONALITY) → PRODUCTIVITY → CAPITAL GAIN

ADDED VALUE IN CLINICAL RESEARCH IN MEXICO: HOW TO ESTIMULATE IT?

➤ QUALITY (GOOD CLINICAL RESEARCH PRACTICES, MEXICAN LEGISLATION) AND QUANTITY (ETHICAL AND RESEARCH COMMITTEES’ AND COFEPRIS’ AUTHORIZATION TIMES) → EFFICIENCY → PRODUCTIVITY = BETTER DRUGS COMMERCIALIZATION AND INFRASTRUCTURE GENERATION → >ADDED VALUE
CONCLUSIONS

- CLINICAL RESEARCH = EFFICIENT TOOL WHICH GENERATES PRODUCTIVITY AND ADDED VALUE FOR THE PHARMACEUTICAL MARKET

- MEXICO = REAL PHARMACEUTICAL AND CLINICAL RESEARCH DEVELOPMENT POLE, IF…

Goal

41  Տարածվող կազմակերպության համար կարևոր է ներկայացնել մեկ պարագայում, որը կազմակերպության նախաձեռնությունը քանզի չի կարողանա քույր լուծումներ բերել.
Strategies

1. National policy to encourage research and development
2. Efficient normativity
3. Strategic linking among the involved players
4. Research and development support and encouragement programs

Policy on Technological Development and Basic and Clinical Research

Implementation of a Government policy for research and development encouraging, with a long-term vision which considers the pharmaceutical sector as strategic for the country
Strategies

Normativity on Technological Development and Basic and Clinical Research

Based on an assertive diagnosis of the sector, it’s urgent to adapt the current regulatory scheme, and turn it into a factor that drives investment and development for innovation and competitiveness.

Therefore, it is suggested that the involved stakeholders work together for presenting concrete proposals based on successful international models.

Strategies

Industry - Academia - Research Centers Effective Linking

In order to increase innovation and competitiveness in the pharmaceutical sector, the linkage must be specific, market-oriented (health care needs), and not limited to the traditional models (academia-industry), involving all the related players according to the stage of research and development, turning then science into health care products and services.
<table>
<thead>
<tr>
<th>Strategies</th>
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<tr>
<td>Technological Research and Development Encouragement</td>
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A scheme that includes an integral encouragement with a broad vision in this field, which takes into account the internationally-proven experiences, that attracts investment generating human assets, infrastructure and virtuous circles which increase the country competitiveness must be developed.