REGULATION OF BIOLOGICAL PRODUCTS IN PERU

THE CURRENT SITUATION

Q.F. Susan Zavala Coloma
Functional Unity of Biological Products
January 29th, 2020
GENERAL DIRECTORATE OF MEDICINES, SUPPLIES AND DRUGS
DIGEMID

SCOPE AND ORGANIZATION

PHARMACEUTICALS PRODUCTS DIRECTORATE
- Medicines, Natural, Dietetic And Others
- Biological Products
- Controlled Products

MEDICAL DEVICES AND SANITARY PRODUCTS DIRECTORATE
- Medical Devices
- Sanitary Products

INSPECTION AND CERTIFICATION DIRECTORATE
- Warehouses and Stakeholders
- Manufacturers
- Control And Surveillance of Products
- Illegal Trade

PHARMACOVIGILANCE, ACCESS AND USE DIRECTORATE
- Access To Medicines
- Rational Use
- National Center of Pharmacovigilance And Technovigilance

Authorization and renewal
- Reviewers: 6 Quality and regional requeriments
- 3 RMP/Safety and Security (*)

Changes Post -Approval
- 2 Reviewers

Batch Release
- 2 Reviewers

FUNKTIONAL UNITY OF BIOLOGICAL PRODUCTS

(*) Area of efficacy, security and quality of Pharmaceutical Products Directorate

Organizational Structure of DIGEMID
http://www.digemid.minsa.gob.pe/Main.asp?Seccion=47
LEGAL BASIS

**LEGAL BASIS**

- WHO
- PANDRH
- ICH
- EMA
- Health Canada
- US FDA

**LEGAL BASIS**

**DIGEMID Date Base - Dec 2019**

**CLASSIFICATION**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood and Plasma derived Products</td>
<td>64</td>
</tr>
<tr>
<td>Immunological</td>
<td>68</td>
</tr>
<tr>
<td>Biotechnological Products -DNAr techniques</td>
<td>164</td>
</tr>
<tr>
<td>Biotechnological Products -Mab and hybridoma</td>
<td>64</td>
</tr>
<tr>
<td>techniques</td>
<td></td>
</tr>
<tr>
<td>Other Biological Products</td>
<td>70</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>430</td>
</tr>
</tbody>
</table>

**DIGEMID Normativity**

http://www.digemid.minsa.gob.pe/Main.asp?Seccion=475

**BIOSIMILARS:**

- Infliximab 100 mg (FLIXCELI CELLTRION INC.)
- Rituximab 100mg/500mg (TRUXIMA CELLTRION INC.)
- Trastuzumab 420 mg (OGIVRI/BISINTEX BIOCON LIMITED)

**S.D. N° 016-2016-SA**

- “Biological Products that opt for the similarity way”

**S.D. N° 011-2016-SA**

- “Biological Products: Biotechnological Products”

**S.D. N° 016-2011-SA**

- “Similar biological product”

**LAW N° 29459**

- PHARMACEUTICAL PRODUCTS
  - “Biological Products”

**DIGEMID**

http://www.digemid.minsa.gob.pe/Main.asp?Seccion=475
ASSESSMENT PROCESS

VUCE Application (CTD - magnetic storage)

Assessment (S & E/RMP)

30 days to prepare response

Assessment (Q and R)

Notification of questions and reports

Response to Notification of questions

Assessment of response (S & E/RMP)

Assessment of response (Q and R)

DECISION

<table>
<thead>
<tr>
<th>CLASSIFICATION</th>
<th>EVALUATION DEADLINES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotechnological Products</td>
<td>Until 12 months</td>
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<tr>
<td>Biosimilar Products</td>
<td></td>
</tr>
<tr>
<td>Vaccines and Immunological Products</td>
<td>Until 180 days</td>
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<tr>
<td>Blood and Plasma derived Products</td>
<td>Until 12 months</td>
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<tr>
<td>Other Biological Products</td>
<td>Until 12 months</td>
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</table>
BIGGEST CHALLENGES

- Regulation pending of approval
- Applicants orientation in new regulations
- More reviewers experts
- More capacitations
- Standardize evaluation criteria among reviewers
- Evaluation process for been a Regional Reference Authority

PRIORITIES

1. NATIONAL ESSENTIAL MEDICINES LISTS
2. BIOTECNOLOGICAL PRODUCTS-BIOSIMILARS
3. VACCINES
Thank you!

Muchas gracias!