Transparency of regulatory decision making – Anvisa’s Perspective

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Mission

➢ To promote and protect population health...

Values

➢ Ethics and responsibility;

➢ Excellency in management;

➢ Capacity for coordination and integration;

➢ Knowledge as source for action;

➢ Transparency
Transparency

Main Strategies and Actions

- Good Regulatory Practices;
  - Improve transparency, the social control of the process and the effectiveness of the norms.

- Regulatory Agenda;
  - Public participation to determine priorities.

- Public Consultations and Public Meetings;
  - Assessment of Anvisa’s norms proposals by anyone.

- Pre-submission meetings;
Main Strategies and Actions

- Consultation of documents analysis status is available at Anvisa’s website;

- Documents lines are disclosed at Anvisa’s website, as well as the average time of analysis for the corresponding petitions.

- General Office of Medicines and Biological Products publishes a Management Report on quarterly basis. This report brings the main actions, productivity, management of the documents lines and other informations.

- Guidelines Publications - Four different in 2015.

- Regulatory Convergence – ICH Working Groups.
• Drug Approval and Refusal Letters

✓ Drug letters are available on Anvisa’s website.

✓ Anvisa’s reasons to approve or refuse a product.
Drug Approval Letters

- Summary of medicine characteristics;
- CMC informations (QC and production) – comparability exercise (biosimilars);
- Non clinical and clinical studies;
- Marketing authorization.
Drug Refusal Letters

- Summary of medicine characteristics;
- Reasons to deny marketing authorization;
- Conclusion
THANK YOU

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