INTERFARMA

Associação da Indústria Farmacêutica de Pesquisa

The 3rd Brazil-Japan Seminar on Regulations on Pharmaceuticals and Medical Devices

Enhancing Review Efficiency of Pharmaceuticals and Medical Devices (Regulatory Convergence)

São Paulo, October 5th, 2016

ブラジルへようこそ

PROPOSAL FROM BRAZILIAN INDUSTRY

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BRAZILIAN HEALTH REGULATORY AGENCY

ANVISA

- ANVISA is a young regulatory agency: 17 years;
- Over this first phase, ANVISA's priority was to enact regulations about all major sanitary aspects;
- The result is very positive: Brazil today has a modern regulation in place, aligned with safety and efficacy principles for medicines.

BRAZILIAN HEALTH REGULATORY AGENCY

CHALLENGES

- While the regulation is good, implementing it faces hurdles, because:
  - ✓ ANVISA's scope is larger than any other agency;
  - ✓ Its structure is small for the activities it tackles;
  - ✓ Although it has a highly competent technical team only now they are starting to get rid of bureaucracy;
  - ✓ Over the past years the Agency has suffered with some political indications for the Board. People who lacked the experience and knowledge needed for the job.

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CURRENT SCENARIO

- Recent months have seen important advancements;
- ANVISA is increasingly getting closer, exchanging experiences and participating in joint initiatives with the world's major regulatory agencies;
- The recent adherence to the ICH is a landmark of this effort;
- The recent Resolution 73, about post-registration of products is aligned with the international regulation. It is a paradigm change – the shared responsibility between the Agency and companies making the post-registration process much swifter;

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CURRENT SCENARIO

- Legislation of biologicals: modern, fair and technically appropriate. Despite many pressures ANVISA has been able to ensure the rigors of the norm, always concerned with quality, safety and efficacy;

- Medicines clinical development dossier (MCDD). With it, Anvisa ensures access to the planning of the worldwide clinical development of a product, a fact that will be key for its decision about the registration of a given product;

- The recent norms enacted by ANVISA show its concern with focusing on what really involves sanitary risk.

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NEXT STEPS

- Implementing a new regulation about clinical trials, enacted to reduce timelines but that has yet to produce the desired effects;
- Adopting the electronic registration system (e-CTD) that is already in place in more than 100 countries;
- Accelerate, with the support of the pharmaceutical sector, the creation of guides/registration requests of more complex products such as biologicals;
- Strengthening the pharmacovigilance system, a sector where ANVISA's lack of structure is specially visible;

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NEXT STEPS

- Establishing a consistent form of support to innovation;
- Continuing to reduce regulatory timelines;
- Ending the successive delays to implement the traceability system of medicines, essential to ensure an ethical and safe marketplace;
- Implementing a resolution that is already approved and that will allow to revalidate product registrations for longer periods;
- Implementing a resolution also approved that establishes the GMP certificate expiration date for up to four years.

THANK YOU

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