



SINDUSFARMA

3º Seminário Brasil-Japão

04.10.2016/ São Paulo

Enhancing Review Efficiency

**Regulatory
Convergence**



Definition

“Regulatory convergence” represents a process whereby the **regulatory requirements across countries or regions become** more similar or “**aligned**” over time as a result of the gradual adoption of **internationally recognized technical guidance documents, standards and scientific principles**, common or similar practices and procedures, or **adoption of regulatory mechanisms** that might be specific to a local legal context but that align with shared principles **to achieve a common public health goal.**

It does not necessarily represent the harmonization of laws and regulations, which is not a prerequisite for allowing the alignment of technical requirements and greater regulatory cooperation.

Source:

<http://www.fda.gov/biologicsbloodvaccines/internationalactivities/ucm271079.htm>

APEC – Asia-Pacific Economic Cooperation

Initiatives and Organizations



- Same objectives
- Technical Guidelines
- Implementation in consistent manner

Benefits

- Regulatory convergence to speed up global access to innovations.
- Patient: More expedited access to medicines ensuring reliable supply
- Ensurance drugs with safety, efficacy and quality standards to patients protection.
- Not all regulators have the resources or capacity to perform all regulatory functions and is possible to alleviate regulatory burden and ensure high quality medical products.

Challenges

- **Low predictability** and **long approval timelines** are other issues with high impact for all companies. Especially, the requirements and timelines for post approval changes.
- Clinical Trials - Regulatory requirements for registration in specific countries- Asia and Mexico, for example.
- Strengthening the capacity of regulatory authorities to regulate in a manner that is consistent with timely access to medicines.
- Complex global regulatory environment.

An Effective Approach to Regulation

Some elements of regulatory oversight can be shared.

- ✓ Evaluation of quality, efficacy and safety

Other elements of regulatory oversight must be local.

- ✓ Licensing decision
- ✓ Local manufacturing oversight
- ✓ Pharmacovigilance
- ✓ Appropriate distribution controls (stability and cold chain)
- ✓ Product security (protection against counterfeiting and adulteration)

Regulatory framework should also be flexible, providing for expedited or waiving of registration in the case of public health emergencies.

Mike Ward Prospects for a more efficient regulatory environment

DIA 2016

SAKIGAKE Process in Japan

- Principles are broadly similar to US FDA Breakthrough Designation Process.
 - Speed review of innovative new drugs.
- “Saki” means “early” or “go beyond”, while “gake” means “run”; Sakigake translated into English means “forerunner review assignment”.
- Sakigake fits in with Japan’s desire to be seen as a world class country for innovation and drug regulation.



Initiatives can be adapted and adopted by other countries

International electronic standards

- **electronic Common Technical Document (eCTD)**

Harmonized electronic interface for the transfer of regulatory information from regulated industry to regulatory authorities.

- **Individual Case Safety Report (ICSR)**

International standard for electronic transmission of Individual Case Safety Reports (ICSR) in order to exchange adverse events and medication error reporting.

Final considerations

- Weak regulatory systems do not serve interests of patients, industry nor the health care system.
- Regulatory system needs to be science based, international standards and best practices.
- True regulatory convergence: alignment of the goals of regulatory authorities and industry.

THANK YOU

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