Brazilian Health Surveillance Agency - Anvisa
&
Brazilian Pharmacopoeia
Global Regulatory Harmonization – Opportunities

Norberto Rech
Brazilian Pharmacopoeia
President

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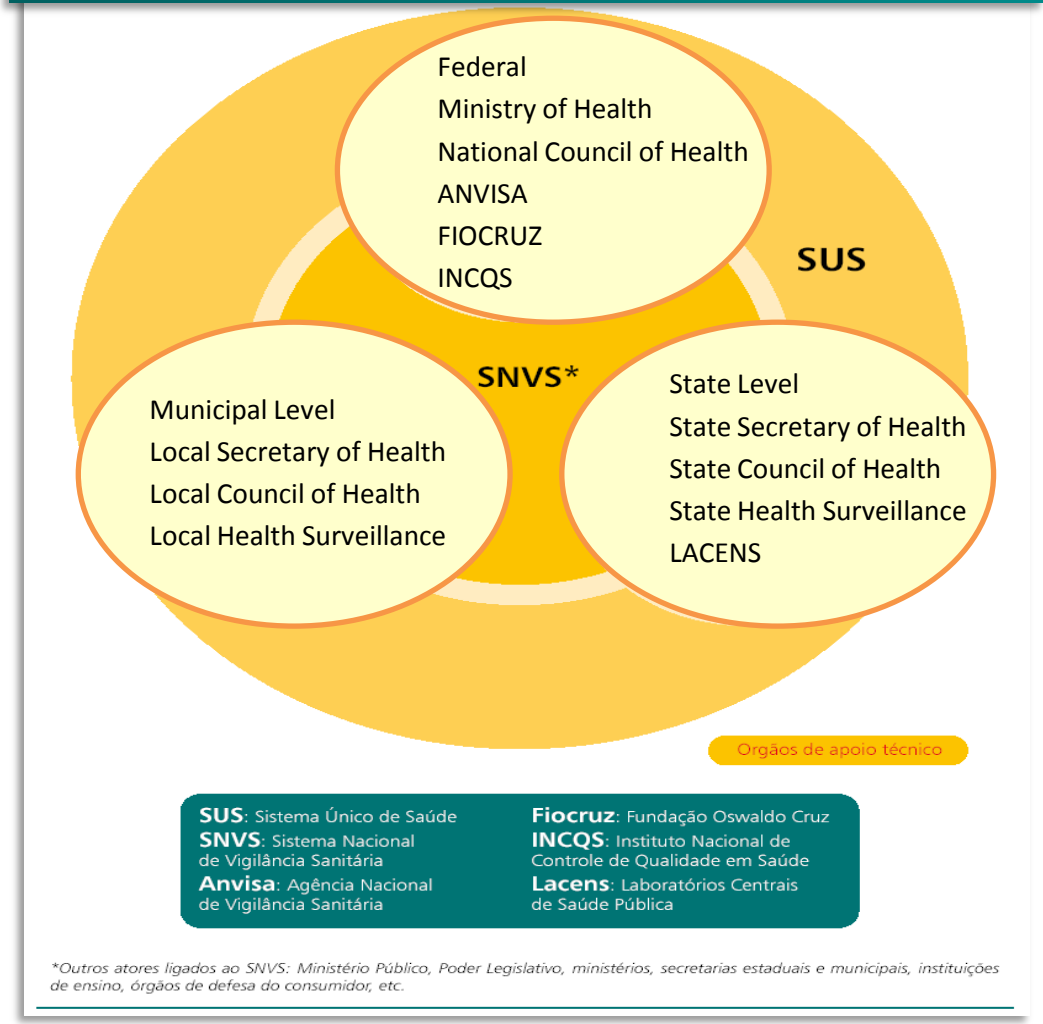
National Health Surveillance System in SUS



► Established by Federal Law 9.782/1999 (Health Surveillance Law 6.360/1976);

►Agency is linked to the Ministry of Health (Federal Public Administration).

►Collegiate Board of 5 Directors;

►Coordinates the National Health Surveillance System (SNVS);

►Headquarters located in Brasilia – DF;

►83 local offices throughout Brazil at ports, airports and borders.

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CURRENT SITUATION

- ✓ Potential Health Risks posed by the complexity of the health product supply chain
- ✓ Multiplication of Efforts
- ✓ Harmonization / Standardization

PRINCIPLES FOR THE FUTURE

- ✓ **Improve the regulation and surveillance global capacity by recognizing, promoting and improving local capacities**
- ✓ **Identify synergies, reunite all efforts and build coalition mechanisms**
- ✓ **Achievement of Adequate Level of Protection**

- ✓ Work closely to strategic partners for the implementation of international technical cooperation, promoting the exchange of experiences and knowledge.
- ✓ Identify synergies, reunite all efforts and build coalition mechanisms.
- ✓ Improve International Technical Cooperation between regulatory authorities and Phamacopoeias.

Periodically define strategies and mechanisms for convergence and harmonization, and support their dissemination, adoption, and implementation by the regional NRAs and Pharmacopoeias

NEW CHALLENGES = NEW PRIORITIES = NEW NETWORK

Strategic Objectives
OPPORTUNITIES

- Cooperation to help countries to establish effective regulatory systems that apply international pharmaceutical regulatory standards progressively and systematically, and contribute to regional regulatory convergence.

- Disseminate the standards that have already been developed and support countries in their adoption and implementation, and update standards that support the development of the NRAs and Phamacopoeias' critical functions.

- Increasing number of new health topics for regulation (such as high - complexity technologies, including biotechnological and genomic products, medical and diagnostic devices).

FARMACOPEIA BRASILEIRA

Strategic Objectives - How to reach it?

- ✓ Take advantage of existing experiences of cooperation between NRA, Pharmacopoeias and of the global harmonization work that is already in place (including the promotion of guidance from major harmonization bodies, Good Pharmacopoeial Practices).

- ✓ Establish communication tools to be used to disseminate the Network's priorities and technical standards.

- ✓ Enhance cooperative relationships with each pharmacopoeia including Japanese Pharmacopoeia, USP, EP and WHO.
  - International information exchange among pharmacopoeias
  - Workshop for training
  - Exchange of experts

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Strategic Objectives - How to reach it?

- ✓ Establish formal cooperation with the Japanese Pharmacopoeia for:
  - Exchange of information
  - Development and sharing of monographs, including all drugs which are important for the National Health Systems.
  - Development of chemical reference substances.
  - Act to make possible the introduction of new knowledge and the latest science and technology.

- ✓ Following the building of the Mercosur Pharmacopoeia and Good Pharmacopoeial Practices.

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