

PROMOTE ACCESS TO HIGH VETERINARY ANTIMICROBIALS QUALITY

The case of Argentina

NATIONAL SERVICE OF AGRI-FOOD HEALTH AND
QUALITY - SENASA



Responsibilities

Directorate of Veterinary Products of SENASA

- Quality assurance of veterinary products (Pre and post Registration)
- Good manufacturing practices
- Traceability
- Integration of the chain of veterinary products to the Argentine Strategy for the Control of Antimicrobial Resistance

In line with the OIE Standards

Quality

"Set of attributes or qualities that constitute the way of being of a thing"

Are basic attributes:

- Identity
- Purity
- Power or wealth
- Effectiveness
- Security
- Stability

Applicable to all products registered in Argentina

Good Manufacturing Practices

Good manufacturing practices:

- System that helps ensure that drugs are constantly produced and controlled by quality standards, ensuring uniformity and repeatability.
- They are the factor that ensures that the products are manufactured in a uniform and controlled manner, in accordance with the quality standards appropriate to the indicated use.
- Includes pharmacovigilance actions

In application in Argentina since 2002

Traceability

Procedures that allow knowing the history, location and trajectory of a product or batch of products along the commercial chain

- Control drug transactions,
- Verifying the origin of them,
- Registering the history of locations and transfers throughout the distribution and supply chain.

Detects anomalies in the marketing chain

In application in Argentina since 2013

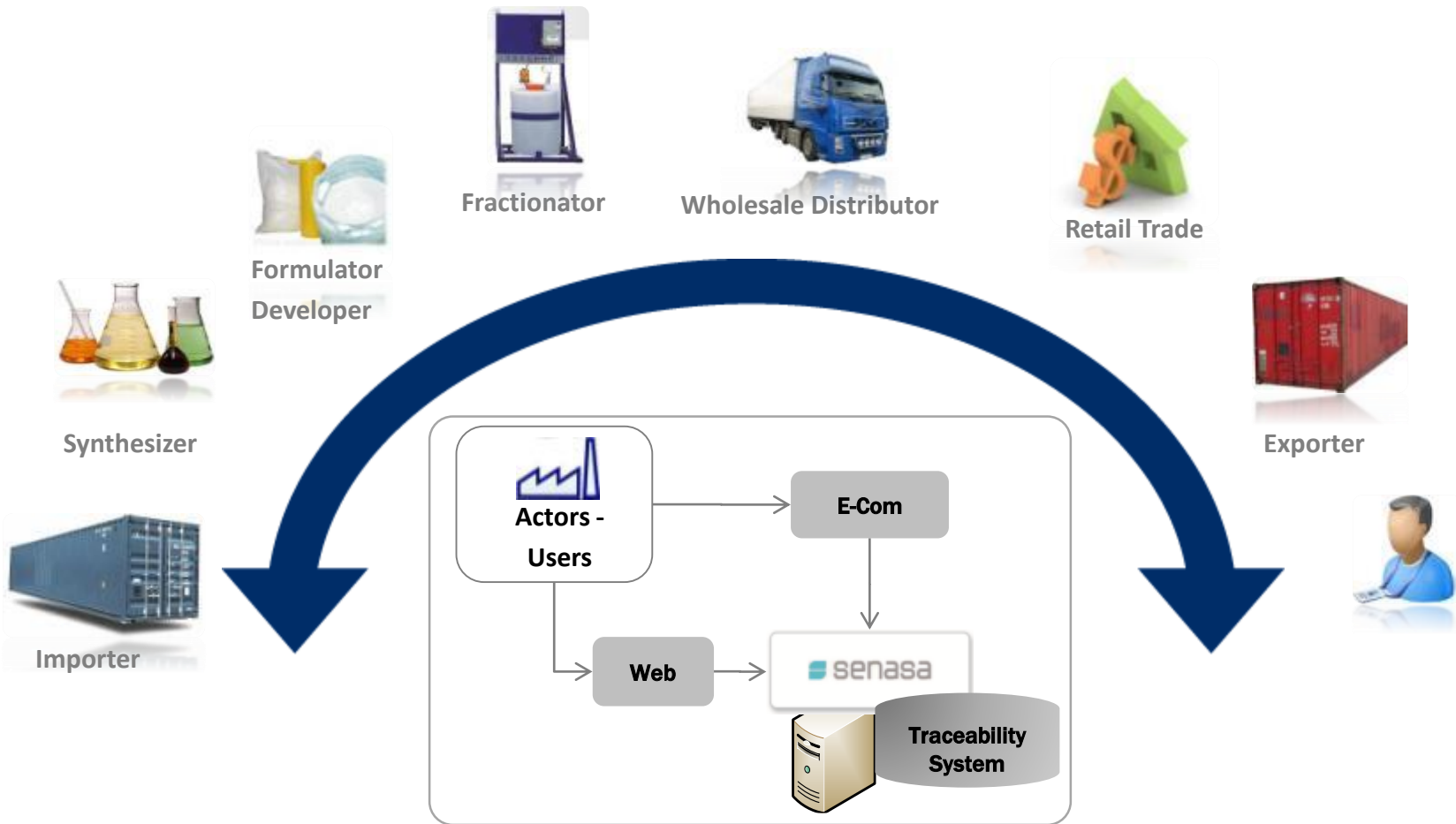
Practical Considerations



- **Verification of compliance with GMP in processing plants.**
- **Random quality controls at retail sites**
- **Marketing traceability system**



Practical Considerations



Traceability System - Actors

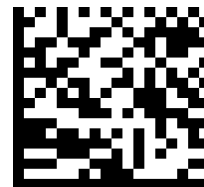
Practical Considerations

Identification options

GS1 128

GTIN	Serie	Lote	Venc.
			
(01)07791234123459	(21)00010	(10)ABC123	(17)120104

GS1
DATAMATRIX



(01) 07791234123459	GTIN
(21)00010	Serie
(10)ABC123	Lote
(17)120104	Vencimiento

- ✓ The capture is done through 2D readers.
- ✓ The numerical capacity is 3,116 digits and
Alphanumeric is 2,335.

The integration of the chain of veterinary products

Integration to the Argentine Strategy for the Control of Antimicrobial Resistance

- Guarantees on the product
- Monitoring of RAM in animals (since 2017):
 - Actions based on scientific evidence
 - Risk Analysis as a basis for decision making
- Participation of all the actors involved
 - National Commission for the Control of Antimicrobial Resistance - "One Health"
 - Equivalence of measures with the Ministry of Health
 - Private sector participation

Thank you very much for your attention

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Secretaría de Agroindustria
Ministerio de Producción y Trabajo
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