

E DEL MOLISE

"G. CAPORALE"



30th Conference of the Regional Commission for Europe

Catania, Sicily, Italy, 7 October 2022

Digitalisation of Veterinary Services
Best practices in Europe
Italy

National Information System for Pharmacosurveillance and electronic veterinary prescription

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National Information System for Pharmacosurveillance

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A project of the **Ministry of Health**, which allows to manage the entire cycle of prescription, dispensing and administration of veterinary medicines and medicated feeds

The project aims to record into a centralized database information relating to the management of treatments in an electronic register, medicines stocks and inventories.



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Digitalization of veterinary medicines

The main purpose of the project is the **complete digitalization** of veterinary medicines management (with introduction of electronic veterinary prescription), thus enabling an effective and efficient pharmacosurveillance action, health risk analysis, with the aim of protecting public health.





Why implement a new information system for pharmacosurveillance?

To combat the phenomenon of antimicrobial resistance (AMR) by ensuring antimicrobial medicines are prescribed responsibly and preventing their overuse.

Monitoring antimicrobial usage in animals should aim at:

- facilitating control and intervention to ensure compliance with developed strategies and regulations on the use of antimicrobials;
- ensuring prudent use of antimicrobials;
- assisting in the interpretation of resistance-surveillance data;
- providing information for research in specific use conditions that govern selection and dissemination of resistant bacteria;
- providing vital information for risk assessment of resistance development at the population level



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Why implement a new information system for pharmacosurveillance?

Simplify operations, through the "dematerialization" of legal obligations related to traceability of use of drugs in veterinary field.





This is achieved with a complete record of all information, allowing all actors, including competent authorities, to have a real-time view of veterinary prescriptions and drug use on animals.

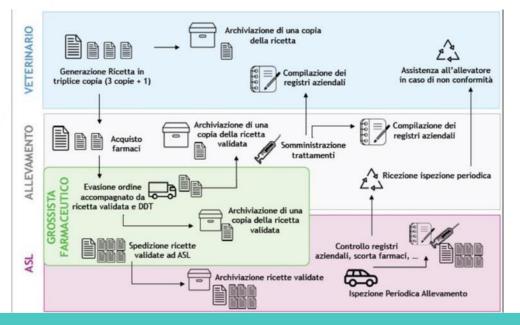
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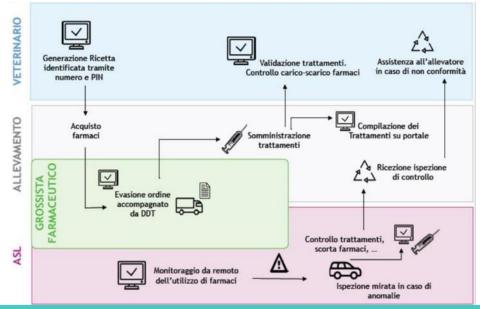
A new model for veterinary medicines management

The e-Prescription is not the simple transposition of the "paper prescription" into a "PDF file", but constitutes a substantial modification of the previous organizational model for the management of veterinary medicines, through the complete digitalization of the management of the distribution and use of veterinary medicines

Before



After



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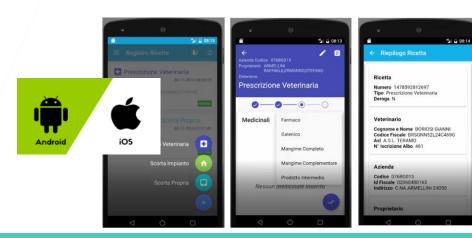
Traceability of veterinary medicines

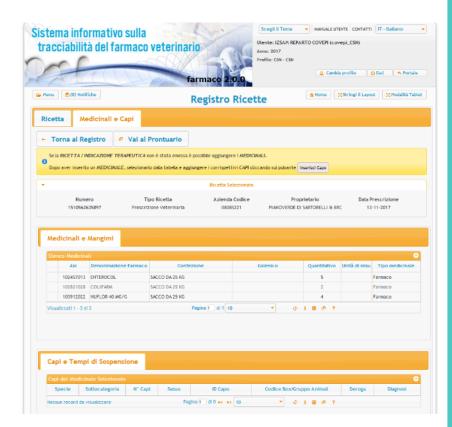






The veterinarian issues the veterinary prescription in electronic format using a normal PC connected to the Internet, or alternatively a mobile device (tablet or smartphone), through an application that simplifies and automates data entry.





Electronic medicine prescription

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Traceability of veterinary medicines

Once issued by the veterinarian, the ePrescription is available online, also on the smartphone of the owner, and can be traced by the respective identification number and a PIN code. The PIN, which changes from each ePrescrption, allows to guarantee the right level of privacy in accessing the prescription data.



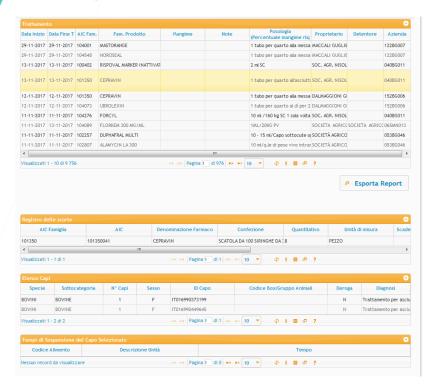


Alternatively, the pharmacy can retrieve the e-Prescription using the corresponding PIN and the ID of the prescription owner.

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Traceability of veterinary medicines

Registration of administration

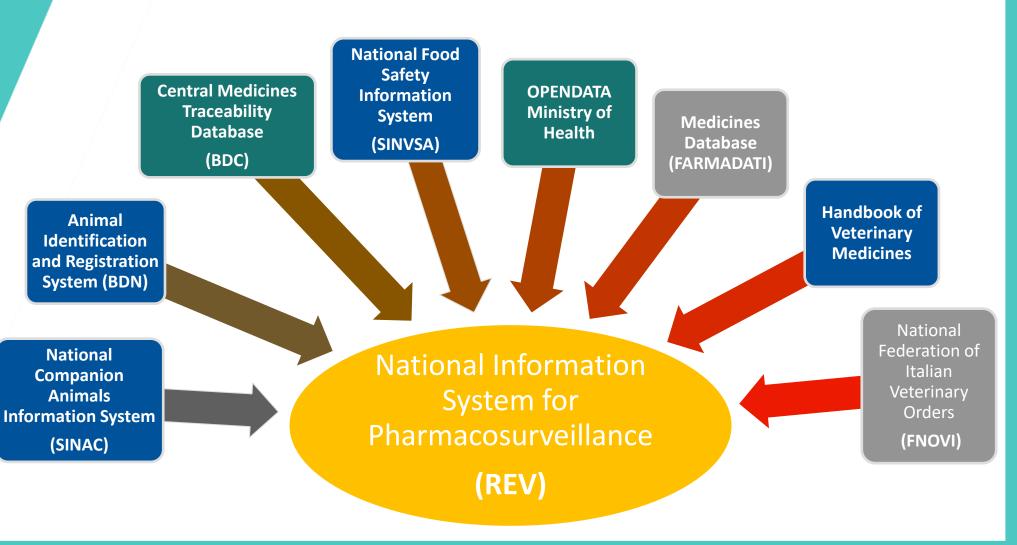


The new system does not introduce new obligations or rules with respect to current legislative norms, indeed its purpose is to simplify and, where possible, reduce the burden on farmers and veterinary, reusing the information already available in other national information systems, and to facilitate the National Health Service in daily operations

Supporting focused and effective AMR control strategies

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Integration with other systems



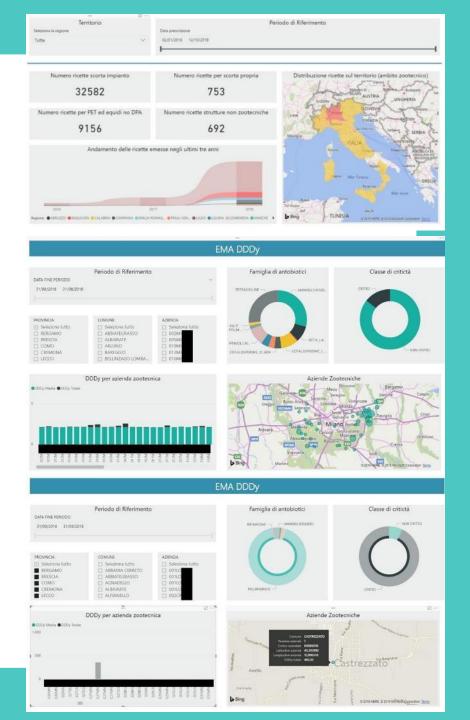
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Integration and data analysis

Additionally to e-Prescription, the National Information System for Pharmacosurveillance foresees the digital management of:

- medicated feed;
- the loading and unloading register of medicinal products;
- the treatments register;
- the report of treatments in the ICA/FCI modules;

The system also includes advanced analysis and reporting system for the competent authorities



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National pharmacosurveillance plan

art. 123, Reg. (EU) 2019/6

The system allows to plan the official control activities, based on risk analysis, in the structures that manage veterinary drugs with the exception of livestock farms.



Then record into the system the results of official controls carried out in these structures as:



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- authorized drugs distributors for direct sale;
- pharmacies and parapharmacies;
- manufacturers of premixes for feed;
- veterinarians authorized to keep stocks;
- veterinary surgeries, clinics and genetic centers;

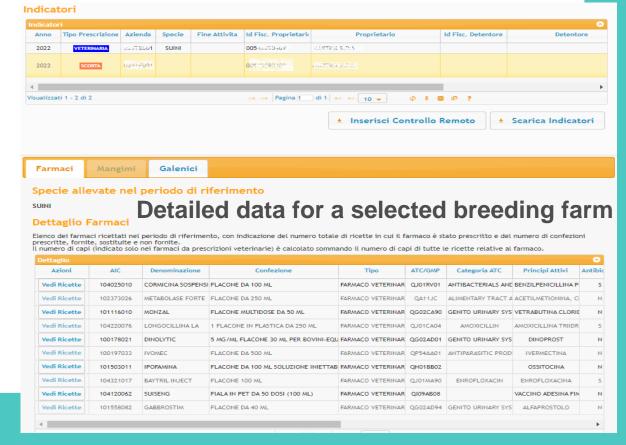
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National pharmacosurveillance plan art. 123, Reg. (EU) 2019/6

The system also allows to verify, record and review the remote (on-line) control activities performed by competent authority on all livestock farms and other structures.

Since these controls exclusively checks the information present and recorded into the system, these do not provide a judgment of conformity or non-conformity, but simply an assessment to decide the need to perform an official on-site control, filling the fields "Completed" or "To be completed in loco"





Data Collection of antimicrobial medicinal products

The system is also used to collect and report, to international organization as WOAH and EMA, both the sales and use volumes of antimicrobial products.

Collection of Data on Antimicrobial Medicinal Products Used in Animals – for EMA art. 57, Reg. (EU) 2019/6





WOAH Annual Collection of Data on Antimicrobial Agents Intended for Use in Animals





Some data about the System

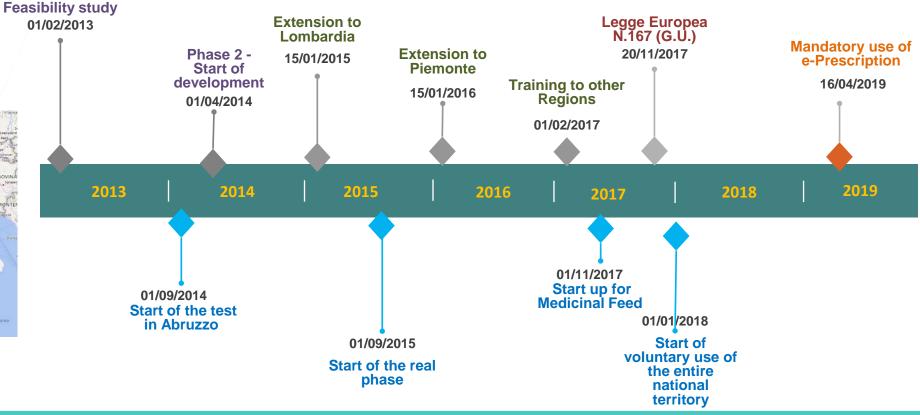
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Phase 1 -



The pilot project

Experimented in several Italian Regions from 2015, the system will be operational throughout the national territory starting from January 2018.



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Use of the system from 2019

Every working day more then 20.000 users access into the system

24.153.078

71.718.239

25.014



No. ePescription



No. of packages dispensed



No. of veterinarians who have compiled at least one ePrescription

128.285

21.695

197



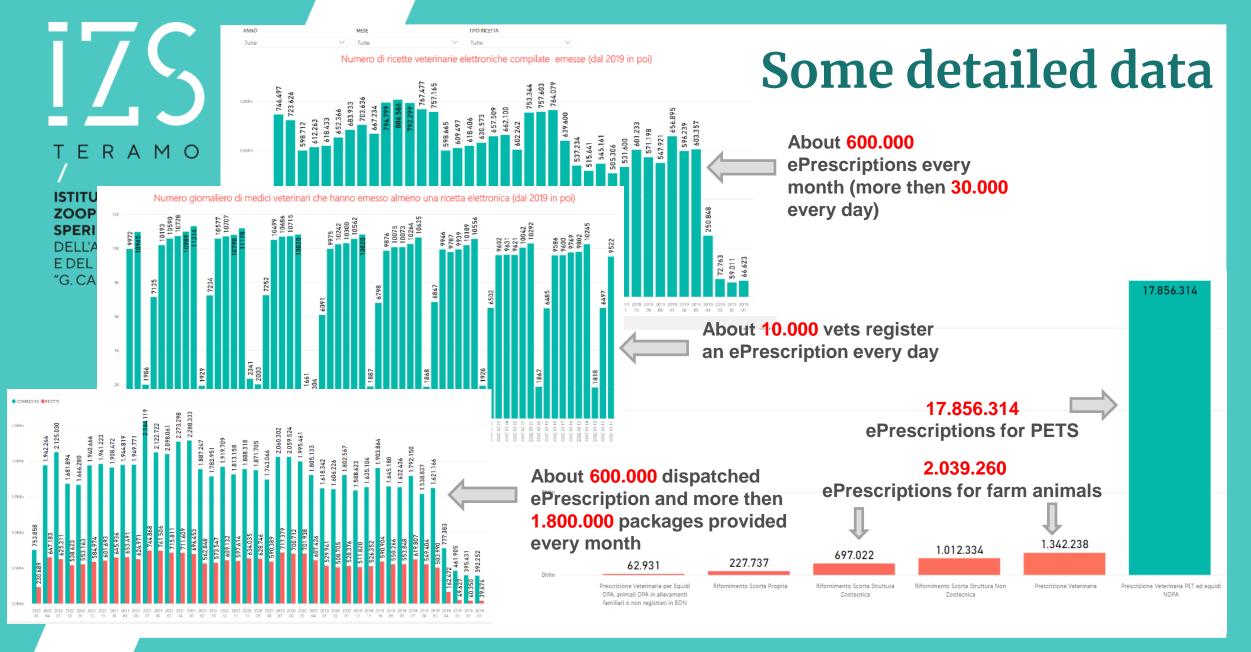
No. of livestock farm that have at least one ePrescription



No. of Pharmacies, Drug-stores ... that have at least one ePrescription



No. of Animal feed operators that have dispensed at least one ePrescription



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Costs and sustainability of the system

Ministry of Health founds the project with about 2 MIn € every year



Permanent Staff of IT Experts

Project Manager, Software Architect, Software Developers, Data Analyst, Database Administrator, etc.



IT infrastructures management

Servers, Storages, Database, Network, Devices, Power Supplies and all Datacenter Equipment maintenance, management and upgrading





Software development and procurement

Developing and procurement of new functionalities an support software for monitoring and security

Data Analysis

Advanced analytics, Business intelligence, machine learning





Software License

For operational system, database, monitoring and security



User Assistance

On line support for users and dedicated call-center by



Training

.Workshop, events,, resident and on-line training for users and operators



Thecnical Support

For Ministry of Health in working groups and in regulation and operational manual definition







Thank you for your kind attention

Any question?

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