
جمهورية مصر العربية
EDA
EGYPTIAN DRUG AUTHORITY
هيئة الدواء المصرية

Registration & Control of Veterinary Medicines in Egypt

Egyptian Drug Authority

The Egyptian drug authority established as an independent body affiliated with the prime minister by law No. 151 in 2019

To take over the functions of the ministry of health, public authorities & government departments

In regard to the regulation of the registration, circulation & control of pharmaceutical preparations, medical supplies & raw material.

Fast track pathway for imported products

*EDA started this new system on 1/9/2020

*Products approved by FDA or EMA will be granted license within 2 months

*Products approved by other competent authorities will be granted license within 4 months

* 20 out of 27 Veterinary Pharmaceutical Products were granted their Final Registration Certificate since the implementation of fast track system

Veterinary products regulated by EDA include:

1-- Any substance or combination of substances used in animals for treating or preventing disease;

or any substance or combination of substances that may be used in animals for restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.

*Regulation is done through **General Administration of Veterinary Pharmaceuticals**

2- Veterinary disinfectants

*Regulation is done through **General Administration of Disinfectants & Pesticides Registration**

Products excluded from the scope of Veterinary EDA regulation:

1- Feeding stuff intended for particular nutritional purpose

*Regulation is done through The Ministry Of Agriculture
(Central Laboratory of Animal Food and Feed Additives)

2-Vaccines

*Regulation is done through The Ministry Of Agriculture
(The General Authority For Veterinary Services)

Laws & regulations governing registration of veterinary medicines:

- Decisions set by the technical committee for drug control.
- Decisions set by the scientific committee for veterinary drugs and feed additives.
- Relevant Ministerial Decrees

Before a veterinary medicine can be legally supplied, sold or used in Egypt it must be registered.

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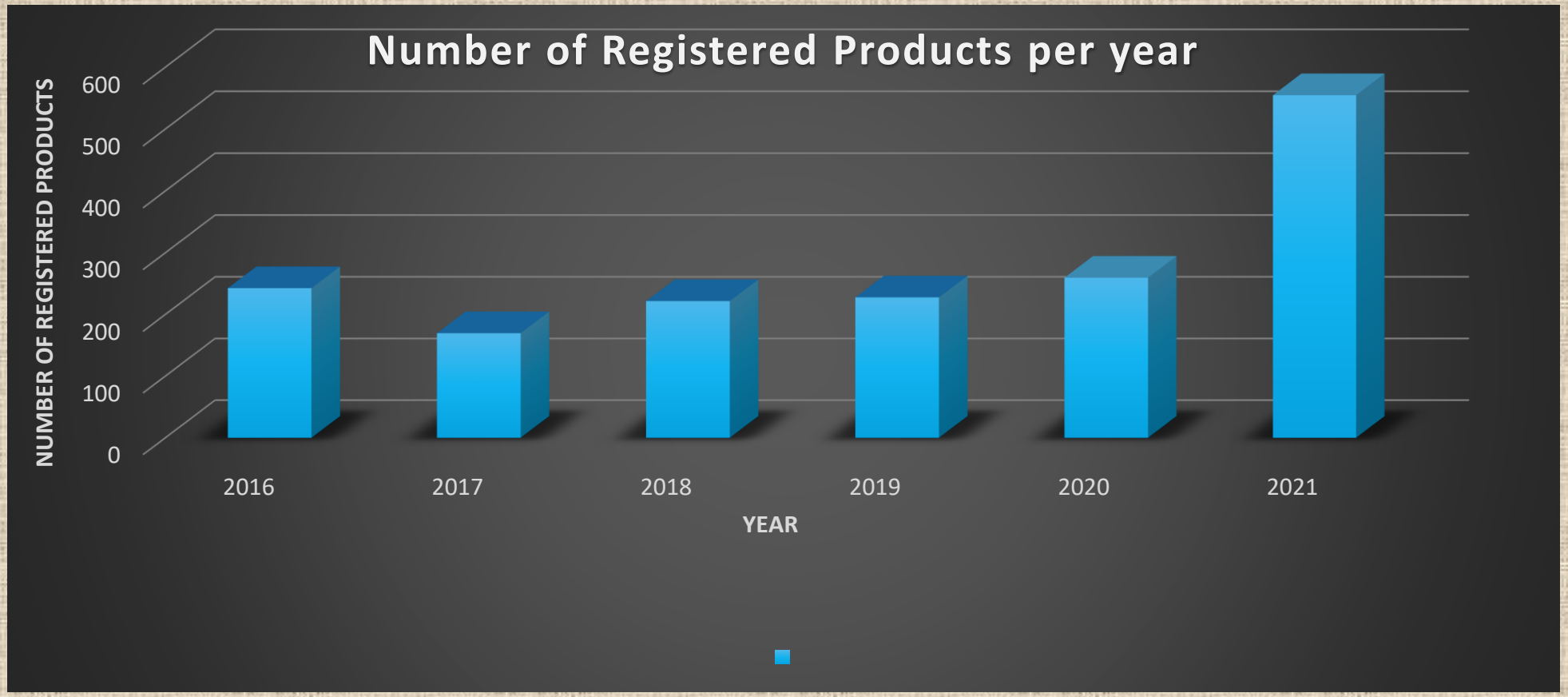
Registration of Veterinary Medicinal Products



Every year hundreds of veterinary medicines are registered in order to be available in the Egyptian marketplace.

How to register a veterinary drug ?

1. Submit an inquiry request
2. Submit a list of suggested names
3. Submit the scientific file
4. Submit analysis file & stability study
5. Submit final registration file to technical committee

How to register a veterinary drug ?

Step 1 :

Submit an inquiry request including reference product , accurately completed application with required supporting documents in order to get an approval on the active constituent in certain concentration and dosage form.

How to register a veterinary drug ?

Criteria of proposed product compared to reference product :

- Same active ingredient
- Same concentration of active ingredient
- Same dosage form

How to register a veterinary drug ?

Step 2 :

*Submit a list of suggested names in order to choose a trade name for the product .

*The product name is chosen according to the Egyptian guidelines for naming of veterinary medicines.

How to register a veterinary drug ?

Step 3 :

Submit the scientific file including information about:

-Target species

-Indication

-Dosage and administration

-Warning and precautions

-Contraindications

- Adverse effects

-Withdrawal period

How to register a veterinary drug ?

Step 3 :

*Scientific file is assessed by the scientific committee for veterinary drugs and feed additives.

* Once file assessment is completed and all criteria are met a preliminary approval valid for 3 years is released .

How to register a veterinary drug ?

Step 4 :

The applicant should do a pilot batch then submit simultaneously;

*-Registration file to the central administration of drug control (CADC) including required documents for quality control purpose.

*- Stability file to the central administration of pharmaceutical products(**General Administration of Stability)**

How to register a veterinary drug ?

Step 4 :

1- CADC registration file :

- Formulation composition describing qualitative & quantitative formulation of the product.
- Physical & chemical properties of the product.

How to register a veterinary drug ?

Step 4 :

- Full details of the analytical method used for determination of the active ingredient , any isomer & impurities.
- Analytical method validation.

*Once CADC file assessment is completed and all criteria are met a certificate of compliance for the product is released.

How to register a veterinary drug ?

Step 4 :

2-Stability file :

includes data that show stability during storage to demonstrate that the product continues to meet its specifications throughout the shelf life of the product, it also contains packaging details.

*Once stability studies are assessed and approved, the product is granted shelf life, storage condition, final packaging material and formulation composition.

How to register a veterinary drug ?

Step 5 :

Complete registration file is submitted to technical committee for drug control for final decision, in case of approval the product is granted a registration number which is a unique identifier for each product and registration license valid for 10 years is released.

The registration of the product is discontinued if:

*Any of the previously mentioned steps were incomplete within assigned due dates.

*Registration file was disapproved by any of the concerned committees during registration process.

*The reference product is withdrawn from the country of origin where it is marketed for safety issues or recent studies

Post Authorization Steps

Renewals :

*Registration license must be renewed every 10 years following initial authorization to remain valid.

*If registration license is not renewed, the validity of the product ends and it will be no longer permitted for release and sale in the market.

*To renew registration license an application should be submitted to the General Administration of Veterinary Pharmaceuticals during the tenth year of product validity.

Post Authorization Steps

Variations:

*For making any change to the registration license a variation application should be submitted to The General Administration of veterinary pharmaceutical (Variation administration)

*Application should be submitted according to Egyptian variation guidelines 2nd edition 2019.

Safety and Efficacy Evaluation

Factors contributing to safety & efficacy of veterinary medicines:

- **API quality**

API quality is evaluated according to the latest version of the substance official monograph or in accordance with its corresponding authentic standard specifications declared by the drug innovator (if not official).

Safety and Efficacy Evaluation

- **Specifications of veterinary medicines**

- Evaluated to ensure that proposed specifications are relevant with the product formula and its intended use

- Quality control tests performed depend on type of product.

Safety and Efficacy Evaluation

- **Stability of the veterinary medicine**

Stability studies are evaluated to ensure that the veterinary medicine shows stability over the shelf life of the product .

- **Manufacturing sites & manufacturing process**

Evaluated to ensure that products are manufactured to high quality standards in EDA-inspected facilities & must meet current “Good Manufacturing Practices” guidelines .

Monitoring And Surveillance

The Central Administration of Operations (Inspection Department) is responsible for monitoring & surveillance through ;

- **Sampling and testing**

*For registered products samples are taken randomly according to inspection department plan.

*For all newly registered products samples are taken from the first three production batches

Samples are taken from the first three production batches

Analysis by CADC/ Review accelerated stability study/ Process Validation

Certificate of compliance is issued by CADC /Accelerated stability study approved

The product is released and allowed to be placed in the market

Still the manufacturer continue the long term stability study.

Monitoring And Surveillance

- **Regular inspection**

*Routine Weekly inspections are carried out .

*Inspection ensures the integrity and reliability of data that support authorization of veterinary medicines and their quality, safety and effectiveness once on the market starting from the raw material and the manufacturing process till the storage of the finished product.

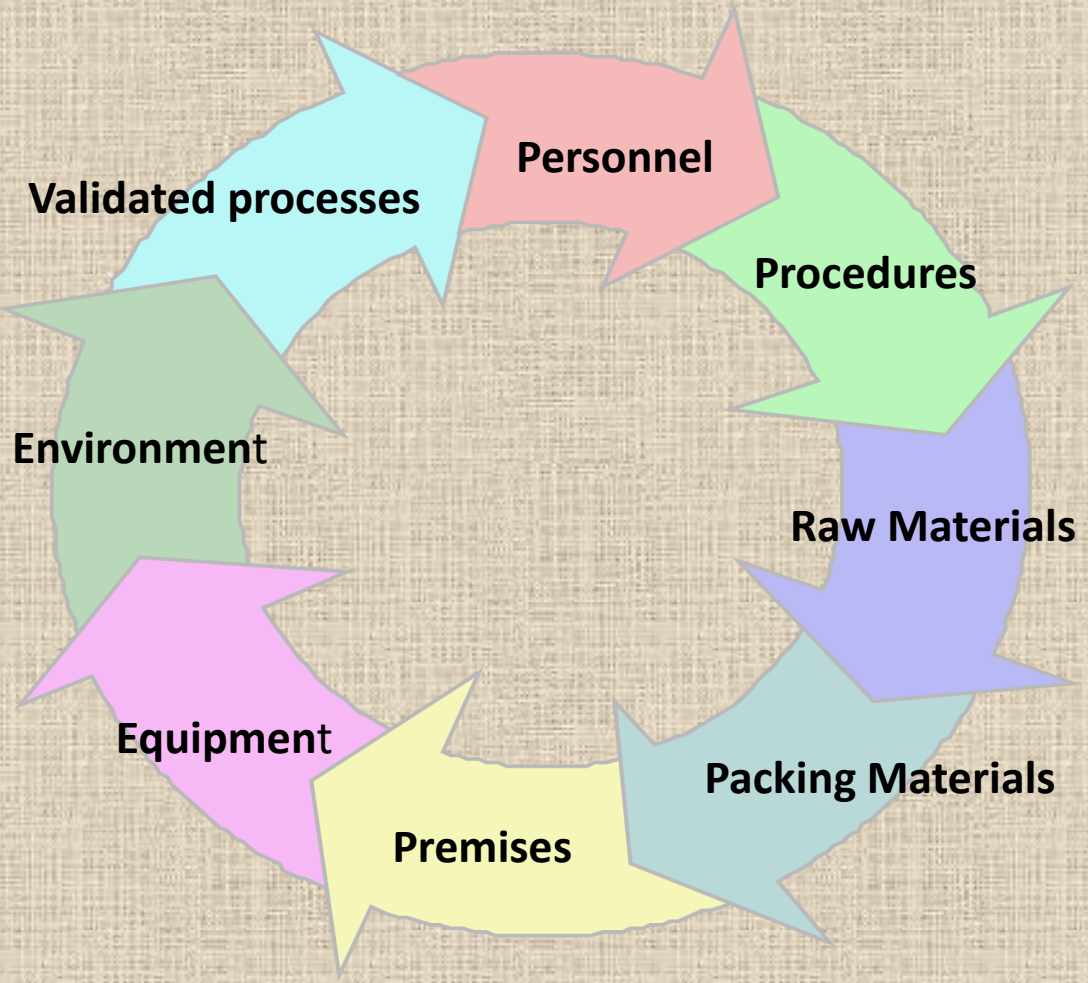
Monitoring And Surveillance

- **Annual Audit**

*According to the inspection department Audit plan all Manufacturing plants should be covered annually.

*Audit Target is to assure the proper implementation of the current GMP in the Manufacturing plant and cover the factors contributing to the quality of products.

Factors Contributing to Quality Products



Monitoring And Surveillance

- **Monitoring marketed product labels**

*Inspection department review copies of labels in manufacturing sites to ensure compliance with the authorization data before products are placed in the market .

Monitoring And Surveillance

- **Recalls**

Recalls are due to any of the following reasons:

*Any product quality defect.

*Any prohibition or restriction imposed by relevant competent authorities.

*Any new information that might influence the evaluation of the benefits and risks of the medicine, issued by relevant competent authorities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Thank you


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