AUTHORISATION PROCEDURE OF A VETERINARY MEDICINE IN THE EU

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INTRODUCTION

Once the investigation of the medicinal product has been completed, in order to commercialize it, the holder must apply for an authorisation providing a dossier demonstrating compliance with the necessary **quality**, **safety** and **efficacy**.

The technical **criteria for the evaluation and authorisation of medicinal products are common to the EU**; each Member State (MS) has to act according to the same rules.

OBJECTIVES

- Identify the different **authorisation routes** for a medicinal product in the European Union and the **agencies** involved
- Overview of the **legal framework** for veterinary drugs.
- Review of the **procedure for authorizing** a veterinary medicinal product.
- Review and summarize the **EPAR** of a veterinary medicinal product, Tilkomay 300mg/ml

METHODS

In order to achieve the objectives described above, a bibliographical review of the legislation in force in this area was carried out, in particular **Regulation 2019/6** on veterinary medicinal products and **Royal Legislative Decree 1/2015,** approving the recast text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices. During the writing of this paper, electronic books and publications were consulted in scientific journals. In addition, the data published by the World Organisation for Animal Health (**OIE**), the European Medicines Agency (**EMA**), the Spanish Medicines and Medical Products Agency (**AEMPS**), the Spanish Association of Generic Medicines (**AESEG**) have also been used as well as the *Boletín Oficial del Estado* (**BOE**). Finally, the Tilkomay EPAR was obtained through the AEMPS database (**CIMAVET**).

REGISTRATION OF AN INNOVATIVE MEDICINAL PRODUCT

1 QUALITY

Qualitative composition

Active principles, excipients and outer casing components

Quantitative composition

Mass of each active principle

According to **GLP** and **GMP**

2 SAFETY

Residue Studies

Maximum Residue Limit (MRL) and withdrawal period

Safety Testing

On animals / people / the environment

3 EFFICACY

Preclinical studies

Pharmacodynamics, pharmacokinetics, tolerance and the emergence of resistant organisms

Clinical studies

Indications, contraindications, instruccions for use and adverse effects

According to **GCP**

REQUIREMENTS FOR GENERIC MEDICINES

- **Identical qualitative and quantitative composition** of the active principle
- **Identical pharmaceutical form**
- **Therapeutic bioequivalence -** Same bioavailability

Compared to the reference medicine

QUALITY

According to **GLP** and **GMP**

Quantitative composition

The quantity of active principle must be **identical**; may differ by a maximum of ±5%

Qualitative composition

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Reference medicine

SAFETY

EFFICACY

Bioequivalence study

The generic drug must generate the **same Area Under de Curve (AUC).** (±0.2).

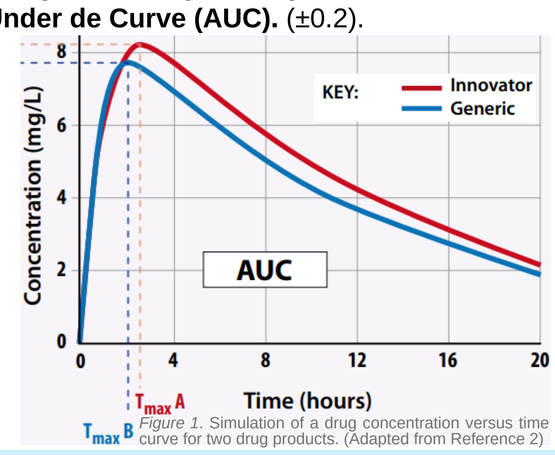

Figure 1. Simulation of a drug concentration versus time curve for two drug products. (Adapted from Reference 2)

AUTHORIZATION ROUTES

CENTRALISED PROCEDURE

ONE

Marketing Authorisation **application**

Evaluation - EMA

Authorisation in all EU MS - EC

Compulsory for: medicinal products obtained by biotechnological processes and veterinary medicinal products used as growth enhancers.

NATIONAL PROCEDURE

The applicant submits to the AEMPS the dossier for the marketing authorisation in Spain.

NATIONAL PROCEDURE

MUTUAL RECOGNITION

DECENTRALISED PROCEDURE

DIFFERENT AUTHORISATION ROUTES: A SET OF COMMON RULES

ASSESSMENT OF TILKOMAY

The **EPAR** of **TILKOMAY 300mg/ml** + 90mg/ml injection solution is reviewed

OBJECTIVE: Verify that it has been **created following the relevant EU legislation**

METHODS:

Notice to Applicants

Article 13b "fixed combination" of Directive 2001/82/EC

CONCLUSIONS:

- It is produced and controlled by methods that guarantee its quality.
- It is safe for the target species, the user and the environment.

BENEFIT > **RISK**

CONCLUSIONS

- The legislation governing medicinal products authorised is complex.
- Behind each authorisation dossier lies a thorough scientific research and a well-developed commercial strategy.
- There is **homogeneity** between the different Member States acting in accordance with the same rules with regard to the authorisation and surveillance of medicinal products.
- There is **transparency** in its operation and in the way decisions are reached.
- The different regulatory authorities of the member states, the European commission and the EMA form a network that make the EU regulatory system unique.
- All the previous points make it possible for humans and animals living in the EU to have access to high-**quality**, **safe** and **effective** medicines.
- Tilkomay correctly follows the current regulations and guidelines required by the EU. This allows to guarantee that presents good quality, safety and efficacy.

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2. Generics. (May 2009). What is bioavailability and bioequivalence?. Best Practice Journal (BPJ), Special Edition. 4-8. https://bpac.org.nz/bpj/2009/generics/docs/bpjse_generics_bio_pages_4-8.pdf

3. Regulation (EU) 2019/6 of the European Parliament and of the Council, 11th of December on 2018, on veterinary medicinal products and repealing Directive 2001/82/EC. *Boletín Oficial del Estado, 4*, 7th of January on 2019.

4. Royal Legislative Decree 1/2015, 24th of July on 2015, approving the consolidated text of the Law on Guarantees and Rational Use of Medicines and Medical Devices. *Boletín Oficial del Estado*, *177*, 25th of July on 2015. https://www.boe.es/eli/es/rdlg/2015/07/24/1/con