

EGGVP Position on the Proposal for a Regulation of the European Parliament and the Council on Veterinary Medicinal Products

PROTECTION OF TECHNICAL DOCUMENTATION

Articles in Regulation: 4, 33, 34, 35

Amendments **supported** by EGGVP:

ENVI Committee: 9, 41, 130, 244, 248, 437, 444, 445, 446, 449, 453, 454, 455, 457

AGRI Committee: 6, 34, 35, 91, 86

Amendments **NOT supported** by EGGVP:

ENVI Committee: 40, 42, 43, 131, 245, 246, 247, 435, 436, 438, 439, 440, 441, 442, 443, 447, 448, 450, 451, 452, 456

AGRI Committee: 87, 88, 89, 90

I- Introduction

The establishment of periods of exclusivity should balance the dual objectives of providing continued incentives for investment in the development of new products, while allowing the generic veterinary medicines' industry to enter the market and creating an appropriate competitive environment.

The Commission proposal for a Regulation on veterinary medicines completely changes the rules for competition between generics and originator products. According to it, generic companies should wait up to 18 years in most cases, as opposed to 10 years now, for the protection period of the originator drug to expire before accessing the market. The proposed policy therefore grants extra protection to originator companies.

The EGGVP fears such proposal will lead to less true innovation and will also bring anticompetitive situations by generating exclusive markets without generic presence for 18 years per product, with consequent price increases. This would create substantial barriers to users not capable of affording expensive originator products, which could be critical in less wealthy regions and production sectors, and for treatment of animals with chronic conditions.

The EGGVP argues that longer periods of exclusivity for originator companies do not result in higher availability, especially for limited markets and minor species struggling to attract the attention of multinational companies. Generic companies are often smaller (SMEs - small and medium sized enterprises) with flexibility for reaching markets that bigger players may not be interested in. The Commission proposal will not leave room for small businesses to enter these niche markets and lead to veterinary drug shortages in these regions for too long periods of time (18 years).

The current 18 year proposal is not proportionate and that is why EGGVP invites MEPs to reconsider it.

II- Commission proposal – negative aspects

The proposal includes provisions for:

- **Cumulative** Protection of Technical Documentation (PTD) up to 18 years (versus 10 years at present),
- **Linked** to the first (global) marketing authorization, and
- **Prolonged** by variations and extensions of existing Marketing Authorisations of the originators (“evergreening strategy”), enabling them **to protect themselves from generics’ competition**.

Real consequences

Less true innovations, but exploitable, dribbling strategy for innovators (multinationals).

Anti-competitiveness, promoting monopolies and obstructing generic development:

- Blocking competitor’s presence in the market influencing viability of the sector with a **negative impact on EU economy and employment**.
- **Lack of sound price competition** resulting in less affordability for users and consumers (negative spillover effect for the food chain).

Reduced availability: Longer PTD does not necessarily result in higher availability, in particular in limited markets that struggle to attract presence from innovators.

- Generic companies are often smaller size (**SMEs**) with **flexibility for reaching markets** that bigger players may not be interested in.

Legal uncertainty, unpredictability for the generic veterinary industry.

Variations of existing marketing authorisations can be strategically submitted at the last minute, providing longer cumulative PTD.

- **Investments already performed** by companies for the development of generic products **will be lost** in such circumstances.

III- ENVI and AGRI Committees: state of play, amendments

- ENVI Committee: A high number of amendments (35 in total) have been tabled by MEPs on this topic. Some aggravate the Commission approach, as they would enable originator companies to more easily gain 18 years exclusivity in the market place without generic competition. Fortunately, several MEPs are aware of the serious consequences this proposals entail, and have proposed a series of amendments to rectify this.
- AGRI Committee: The Protection of Technical Documentation has been highlighted by AGRI Committee rapporteur, MEP Marit Paulsen, as a priority area, due to the important consequences on availability of medicines and free choices for farmers at an acceptable price. On 15 July 2015, the MEPs of the AGRI Committee adopted three compromises ([Compromise 2](#), [Compromise 8](#) and [Compromise 9](#)) on this subject.

IV- EGGVP Proposals

EGGVP is in favour to an amendment of current legislation to include provisions for granting PTD for new relevant technical data supporting the addition of animal species, indications with a significant clinical benefit and new withdrawal periods, as long as **the granted PTD is:**

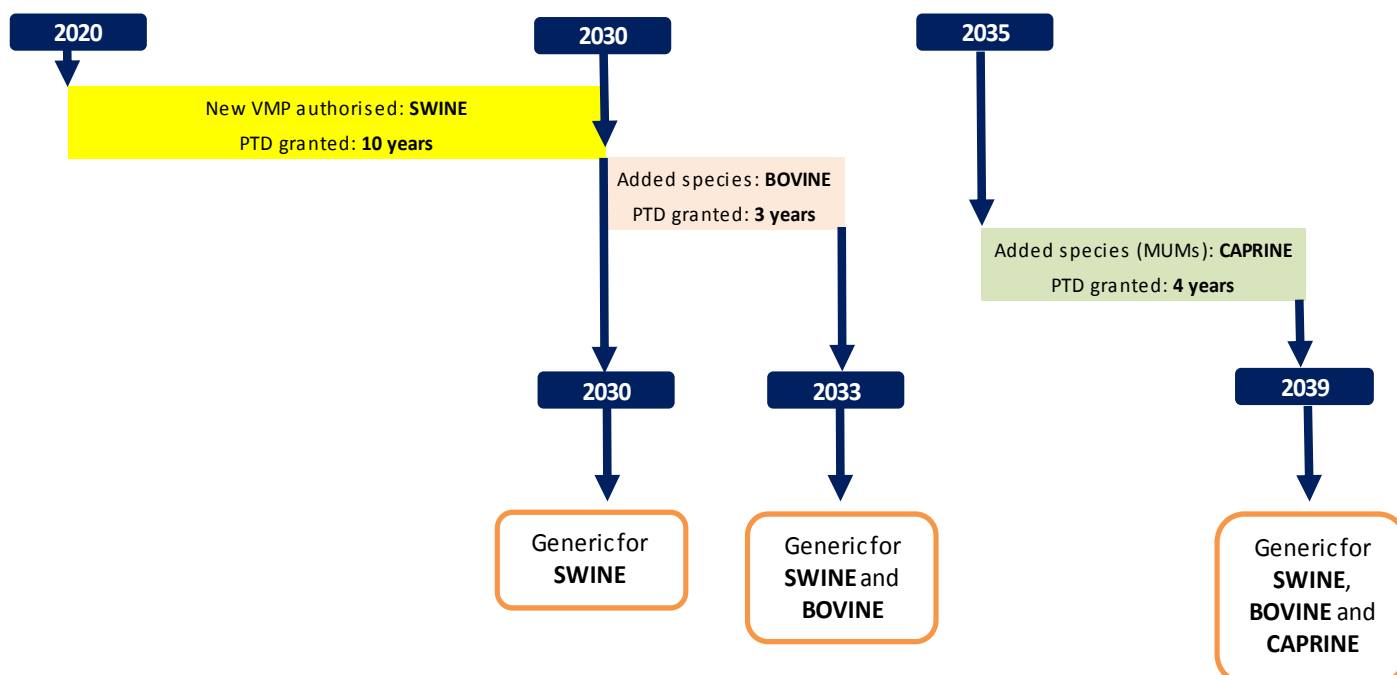
- **Proportionate to the investment, and**
- **Just linked to the extent of the new technical data.**

1. Any protection **should solely be possible for the specific technical documentation** and not for a global marketing authorization in general (**non—cumulative**).
2. PTD should be **equally applied** to new technical documentation on existing veterinary medicinal products developed **by generic or originator** companies.

Detailed proposal

Initial PTD granted: 10 (8 + 2) years	
Afterwards: Non-cumulative PTD periods for each innovation only (for originator or generic veterinary medicines company), not for the original Marketing Authorization , as follows:	
MAJOR SPECIES	MINOR SPECIES
3 years for additional major species 2 year for new withdrawal period 1 year for additional indications with significant clinical benefit	18 years for bees 4 years for MUMS (except bees)
Without any restrictions with respect to time-point of submission	

Example



EGGVP - GENERIC VETERINARY INDUSTRY IN EUROPE

- Mainly composed of **small and medium sized companies**.
- Total **turnover** in 2013 over **€ 1.2 billion**.
- Total number of employees in 2013 circa **5.000 employees**.
- **23 direct associate companies**, marketing authorisation holders of generic veterinary medicines.
- Headquarters of all EGGVP companies located in EU Member States (**EU employment**).