

Generic and added value veterinary medicines entering a new era

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Access VetMed

- Founded in 2002 as the European Group for Generic Veterinary Products (EGGVP)
- Represents the generic and added-value veterinary medicines industry in Europe
- 26 members headquartered in Europe, largely SMEs
- 22 out of 26 members are "veterinary only" companies

We support animal health by
increasing access
to veterinary medicines,
many for minor species and
smaller markets in Europe.

Reg 2019/6, a long journey

- First talks revision Directive back to 2005.
- New/modern piece of legislation was needed, tackling new challenges and needs from society, embracing the One Health concept.
- Our main drivers:
 - data protection formulas
 - o environmental risk assessment
 - o antimicrobial resistance
 - o administrative burden
- Long and evolutive process, with many (new) topics coming in.
- Our industry segment evolving hand-in-hand with the legislative process.



Boost for generic and added value meds

Reg 2019/6 as a catalyst in our sector to take action:

Periodic data analysis, to evaluate the status quo for generic and added value veterinary products in Europe by generating reliable data and highlighting the importance of this segment of Industry. First data available on generic veterinary medicines.

• **Driver**: uncertain impact of new legislation on the development of generic VMPs and on the viability of this industry segment.



Generic marketing authorisation holders in Europe



1/3 of total European animal health market



1/2 of animal health sector employees



Presence in all European markets



Increased availability and access

- The number of generic marketing authorisations steadily increasing
- 50% of all the EU authorisations:
 - o minor species, over 10%
 - o limited markets, smaller geographical areas

Opening central procedure for generics: opportunity

Access VetMed increasing R&D - hybrid marketing authorisations





Impact of the regulation in our sector

- The objectives of the new Regulation are fully endorsed by Access VetMed.
- Increased availability of veterinary medicines across Europe.
- Implementation phase: now it's time for all of us rowing in the same direction and make all efforts to reach the objectives: We are not there yet!
- Important role from National Competent Authorities through national legislation to complement implementation and adapt new rules using pragmatic approaches.
- Periodic evaluation (impact, objectives) would be needed and welcome.



Our wishes for the future

- **Data protection**: proportionate formulas allowing incentives to innovation but also incentives to competition, economy and access to veterinary medicinal products.
- **Environmental risk assessment**: smart approaches towards effective environmental protection while avoiding unneccesary tests and waste of resources.
- Antimicrobial resistance: science-driven measures to fight against resistance while preserving access to effective treatments and safeguard public health, animal health and animal wellbeing.
- Administrative burden: increased efficiency though digitalisation (UPD, EVVET3) regarded as a great opportunity to reduce administrative burden, also towards increased transparency.



Access VetMed mission

"To increase the ACCESS of veterinary medicines to veterinarians, farm and companion animal owners in Europe.

By interacting with authorities, decision-makers and other stakeholders in the EU, we aim at achieving sustainable animal health policies and legislation."



Thank you

