



EMA Roundtable meeting with stakeholders on the 10-year anniversary of the SME Office

EGGVP comments

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About EGGVP, SME status

- **23 direct associate companies**, MAHs of generic VMPs
- EGGVP membership **mainly composed of SMEs**. Mean data 2013:
 - average yearly turnover: 55.000.000€
 - average number of direct employees: 203
- **Recent survey** to 23 EGGVP Members: 8 companies do not qualify for SME status, 15 companies do qualify:
 - 8 companies registered in EMA SME office
 - 7 companies not registered. Reasons:
 - Lack of awareness (new EGGVP members)
 - Complexity of registration procedure
 - Only NP, MRP, DCP
- **Note:** threshold turnover €50 million (Regulation from 2003). Updated according to EU growth rates?

Main challenges for SMEs

- **Strong regulated** environment
- Cumbersome bureaucratic and **administrative** procedures
- MRP/DCP: **country specific** demands
- CP: **fees and resource** demands
- Access to **information**

Only a small part of the SME veterinary sector able to identify and exploit the opportunities?

SME office: incentives

- **Fee** deferrals and reductions, conditional exemptions
- **Support** by EMA's SMEs office: regulatory and administrative assistance
- **Translations**
- **Communication:** e.g. SME User Guide, SME newsletter
- **Workshops** are free and well valued / recommendable

***Great initiative; congratulations on your
10th anniversary!***

SMEs wishes for the future

- SMEs initiatives not only at EMA: also at **National level**? Additional support for **MRP and DCP**?
- **Training / workshops**: larger differentiation between human and vet. One workshop/yearly **for vet SMEs**?
 - ✓ Suggestions: Training on dossier preparation, e-submissions...
 - ✓ Non-presential / telematics?
- Direct **fee reductions** with regard to a **grant of a MA**?
- Smart regulation: **better law-making**, reduction of unnecessary requirements / administrative burden

New VMPS regulation

Strengthening SMEs competitiveness? Improving availability?

- Current provisions on **extended exclusivity periods** for originator products will clearly limit and restrict the competitiveness of generic MAHs (SMEs).
- Extending **obligation of CP for generic VMPS** may damage SMEs.

Will this increase **availability**? Limited markets?

SMEs have more flexibility for reaching markets that bigger players may not be interested in.