

EMA SME OFFICE

A success story in the veterinary medicines sector and opportunities

Veterinary Medicines' stakeholder
contribution to the EMA SME Office 20th
Anniversary Roundtable

European Medicines Agency, 17 October 2025

Presented by Elsa Vecino



Association of Veterinary Consultants

SMEs in the veterinary sector

Over 400 Marketing
Authorisation Holders of
VMPs in the EU*

Narrower and less
specialized portfolio

Limited internal resources in
a complex EU Regulatory
environment: SMEs often
rely on external consultants

Pharmacovigilance
obligations and post-
authorisation lifecycle
management:
disproportionately
burdensome for SMEs

Regulatory fees: Even with
EMA's SME fee
reductions/exemptions, fees
and translation costs remain
heavy for SMEs

Vet SMEs: imbalance between regulatory/operational obligations and limited resources, narrower product portfolios, and smaller markets. This makes compliance, innovation, and competitiveness much harder, even with existing EU incentives.

**source: EU Veterinary Medicines information website*

Support from EMA SME office

- ✓ Translations services, and fee deferrals and reductions are highly valued and most useful
 - ✓ Time and cost savings
 - ✓ Help make decisions regarding development and submission
- ✓ Regulatory advice and administrative assistance considered competent and quick

WITH MANY THANKS AND CONGRATULATIONS ON YOUR 20th ANNIVERSARY

Communication and awareness

- ✓ Limited awareness: SME status not well known, especially by small/new companies.
- ✓ User guide: important first reference document
 - too long and technical: needs simplification, provide practical examples
 - split human from vet information. Since VMR 2019/6: vet and human landscapes have evolved in a different way
- ✓ The annual “vet-only” SMEs workshops and webinars are missed

- Reinstate Vet SME Days at EMA (annual)
- Improve SME User Guide
 - Clear explanation of process steps and timelines – workshop?
- Further involve industry associations – increase dialogue

Reduce registration burdens at SME office

- ✓ Registration procedure considered complex
 - ✓ Annual SME renewal is too frequent and burdensome
 - ✓ Admin burden has highest impact on SMEs
-
- Propose 3–4 year validity for micro/small companies

Fee Incentives: increase clarity

- ✓ Uncertainty remains around applicable fee reductions
- ✓ Provide practical examples for the various fee incentive categories

- Clearer overview for veterinary SMEs
- Include examples for NP/MRP/DCP-focused MAHs

Update SME definition

- ✓ SME criteria unchanged since 2005
- ✓ Outdated MAHs lost status due to organic growth over last 20 years

- Adapt turnover thresholds to reflect today's reality
- Proposal to introduce 'Small Mid-Cap' category
 - Ensure access to SME incentives for this category

Conclusions

- ✓ SMEs are essential players in veterinary medicines but face disproportionate regulatory and resource burdens
- ✓ EMA SME Office support is very valuable
 - ✓ Practical incentives and advice make a real difference
- ✓ 20 years of strong EMA support for SMEs
- ✓ Act on opportunities: simplify and clarify processes, modernise SME definition, ensure fee incentives remain effective.
- ✓ Commit to partnership: EMA and industry working together to keep the system fit for the next 20 years and to secure a successful SME sector.



Association of Veterinary Consultants

THANK YOU