



VETHELLAS SA

Commission Regulation (EC) No 2049/2005

- **EMA**
roundtable with stakeholders
on the 20th anniversary of the
SME Regulation

Vethellas S.A., is a small Greek-owned enterprise engaged in the research, development, and production of veterinary pharmaceutical products at its own facilities in Larissa, Greece. The company operates both domestically and internationally, with 45% of its sales stemming from exports. This year, Vethellas proudly marks its 40th anniversary since its establishment and, as an SME, is particularly grateful for the opportunity to present its proposals on the occasion of the 20th anniversary of Regulation (EC) No 2049/2005.

- * Enhanced national authority staffing in order to strengthen the presence and operation of small businesses (SMEs) at the European level

- * Extra EU fees reductions for SMEs located in small EU-countries, like Greece

- * Direct access to EU-funds, dedicated for SMEs, aimed at supporting research/ new product development

- * Support SMEs producing generic VMPs to ensure cost-effective, high-quality veterinary care

Support from EMA SME office

▼ Major Milestone Achieved

VETHELLAS, with the support and guidance of the European Medicines Agency (EMA), has reached a key milestone in its journey within the veterinary pharmaceuticals sector:

✓ Central Marketing Authorization granted for PRAZIVETIN — the first product in EU designed for use against Gilthead sea bream sparicotylosis.

▼ Highlights:

- Significant achievement in regulatory approval
- Strengthened position in the European veterinary market
- Expansion into the aquaculture segment

▼ EMA Support Areas

The EMA provided valuable assistance to VETHELLAS throughout the process, including:

- Guidance on regulatory strategy and procedures
- Support in scientific and technical documentation
- Scientific advice on quality, safety, and efficacy requirements
- Collaboration during assessment and review stages
- Continuous communication ensuring compliance and transparency
- Translations services free of charge

VETHELLAS extends its sincere thanks to the European Medicines Agency (EMA) for its valuable support — and congratulates the Agency on its 20th anniversary of the SME Regulation