EMA Roundtable with stakeholders on the 20th anniversary of the SME Regulation

HUMAN PHARMA

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General discussion themes

Tailored Regulatory Support for SMEs

EMA's SME Office has played a pivotal role in de-risking early development by providing tailored regulatory advice, scientific guidance, and financial incentives that address the specific needs of smaller developers.

SMEs have consistently **benefited from early-stage scientific dialogue**, **particularly through the Innovation Task Force and PRIME schemes**, which help align development plans with regulatory expectations.

The **fee incentives and procedural guidance have eased entry into the centralised regulatory system**, reducing upfront barriers for first-time applicants.

Training initiatives and SME-specific engagement have **empowered companies with limited regulatory expertise to progress confidently**.

However, continued gaps remain in awareness and uptake of available EMA services, particularly for medical device-sector SMEs.

Navigating Regulatory Overlap and Complexity

The convergence of multiple EU regulatory frameworks has created an increasingly fragmented and burdensome environment, disproportionately impacting SMEs that lack dedicated regulatory resources.

1. Broader **operational uncertainty is driven by evolving horizontal initiatives** such as ESG reporting requirements, the Omnibus legislation packages, and the pending adoption of the revised General Pharmaceutical Legislation.
2. **Overlap between CTR-MDR-IVDR imposes a cumulative regulatory burden** that stretches the limited capacity of SMEs.
3. SMEs operating in fast-evolving fields often face **challenges in understanding how emerging regulations interact,** especially in the absence of coherent guidance.
4. The introduction of a **cost-based EMA fee model has raised concerns around proportionality and predictability for resource-constrained innovators**.
5. Smaller companies at or just beyond the SME threshold **struggle to access support due to rigid eligibility criteria.**
6. **Regulatory fragmentation across Member States** compounds the administrative burden and undermines the benefits of centralised support.

Future-ready Innovation Ecosystem for Life Science

SMEs are at the forefront of therapeutic innovation in Europe, yet their ability to scale and compete globally depends on a regulatory environment that proactively embraces new technologies and business models.

Scientific advice and regulatory flexibility have helped SMEs navigate complex modalities such as ATMPs, digital therapeutics, and platform technologies.

The **lack of harmonised regulatory approaches across EU Member States** limits the uptake of innovative trial designs and manufacturing solutions developed by SMEs.

Delays in clinical trial authorisation and inconsistent implementation of digital tools hinder SMEs from advancing at competitive global speed.

The **absence of proportionate incentives for incremental innovation** weakens long-term investment in SME-driven R&D.

Stronger integration of regulatory science with EU research funding frameworks would **amplify SME contributions to unmet medical needs.**

Future steps / initiatives

Proposed initiatives

Building on initiatives from the European Commission – such as the Competitiveness Compass, the Life Sciences Strategy, and the ambitions outlined for upcoming Biotech Act by the Commission – we propose three key actions to enhance competitiveness for our SMEs and strengthen the preparedness of the European Medicines Regulatory Network.

1. Revision of the SME Regulation (EC No 2049/2005)
2. Establishment of a Centralised Innovation and Access Helpdesk
3. SME-Centric Horizon Scanning and Foresight Mechanism

1 Revision of the SME Regulation (EC No 2049/2005)

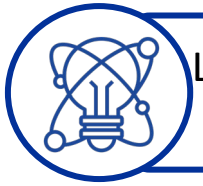
The current SME definition and scope no longer fully reflect the complexity of today's life sciences ecosystem.

A revision could:

Introduce a "small mid-cap" category – as announced in the Commission's competitiveness compass and the Single Market- for growing companies that face SME-like constraints but exceed eligibility thresholds.

Facilitate eligibility for incentives to innovation-driven entities such as academic spin-outs and non-profits.

Enable more dynamic eligibility criteria based on R&D intensity or therapeutic focus (e.g. rare diseases, AMR, ATMPs).



Link regulatory support more closely with the stages of innovation, allowing tailored assistance from discovery to access.

2 Establishment of a Centralised Innovation and Access Helpdesk

SMEs continue to face challenges in navigating the fragmented EU regulatory and access landscape, particularly when transitioning from early development to authorisation and market access.

A centralised, multi-agency helpdesk would act as a practical tool to operationalise the goals of the Life Sciences Strategy & the upcoming Biotech Act by supporting SMEs in real time.

- Designate a **single coordinating body or platform to oversee the joint review by national competent authorities for medicines** and Notified Bodies for devices as applicable.
- Establish a **centralized coordinated procedure supporting SMEs** to address the fragmentation and support continuity of knowledge building **from trials through marketing authorization processes and even into the post – marketing authorization**.
- **Cross-sector support**, including for drug-device combinations, digital therapeutics, and diagnostics
- **Streamline lifecycle coordination via EMA with increase harmonization and alignment between regulators, HTA bodies and payers** on data acceptability and methodologies for biopharmaceuticals throughout the development pathway.
- Fast-track **support for SMEs developing treatments in key strategic areas for the EU** such as rare diseases, antimicrobial resistance, paediatrics, pandemic preparedness.

3 SME-Centric Horizon Scanning and Foresight Mechanism

The EU Innovation Network and other bodies conduct horizon scanning to inform regulatory science priorities, but these processes often reflect the perspectives of larger actors or public institutions.

A dedicated mechanism to include SME input would ensure that the regulatory system keeps pace with front-line innovation emerging from smaller developers.

- **Standing SME advisory panel embedded in EU-level foresight initiatives to share insights on technological trends**, pipeline evolution, and bottlenecks.
- Early **signal-sharing mechanism that allows SMEs to confidentially highlight scientific or regulatory challenges** before they become systemic issues.
- Alignment with **EMA's Regulatory Science Strategy and EMANS 2028, ensuring SME perspectives shape the development of new guidelines**, tools and review models.
- Collaboration with academic incubators and innovation clusters **to capture early-stage insights from translational research and spin-outs**.
- Feedback **loop into funding and infrastructure planning**, helping ensure EU research and financing tools match the evolving needs of SME innovators.