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Regulatory Science and Innovation Task Force

Report on the European Medicines Agency roundtable with stakeholders – 20 years supporting SMEs

17 October 2025

1. Introduction

To mark the 20th anniversary of the implementation of the European Medicine Agency's (EMA's) small and medium-sized enterprises (SMEs) regulation[1], EMA held a roundtable meeting with stakeholders on 17 October 2025. The objectives of the meeting were to provide an update on the EU support to SMEs, highlight the achievements of EMA's SME initiative, present the results of an SME survey launched in 2024 and exchange views on achievements, challenges and future opportunities to strengthen support to SMEs and innovation in the pharmaceutical and MedTech sector.

Participants included representatives of the European Commission (EC), the European Medicines Regulatory Network, funding entities, life science incubators, patients' organisations, industry organisations and SMEs.

EMA's Executive Director Emer Cooke opened the session by highlighting the Regulation's pivotal role in driving healthcare innovation across Europe. Since its adoption in 2005, the initiative has supported over 2000 SMEs through tailored regulatory assistance, fee reductions, and scientific advice, helping bring life-saving therapies to patients. While the regulation clearly achieved its objectives in supporting SMEs developing innovative medicines, certain challenges continue to particularly impact SMEs such as regulatory complexity, funding gaps, and global competition. EMA's vision is to create an environment where innovation can thrive, enabling a fast path from innovation to safe and effective human and veterinary medicines, through regulation, communication, and collaboration with stakeholders including patients, researchers, industry, and international regulators.

The roundtable was chaired by Emmanuel Cormier, Head of the EMA Regulatory Science and Innovation Task Force and Constantinos Ziogas, Head of the EMA SME Office.

2. EU policies supporting SMEs and innovation (session 1)

The first session of the roundtable focused on the broader EU policy and funding landscape supporting SMEs in the life sciences sector. Representatives from life science incubators and patient organisations shared their insights on how current and future initiatives can better address the needs of innovative SMEs. The session was chaired by Leonor Enes, from the EMA SME Office.

[1] Commission Regulation (EC) No 2049/2005

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Eszter Batta, representing the European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), opened the session by underlining the critical role SMEs play in ensuring pharmaceutical resilience and driving innovation across the EU. She presented barriers and challenges identified by SMEs in the 2025 Eurobarometer survey and the Commission responses to address them such as simplification measures embedded in new legislative proposals, including SME-friendly clauses, phased implementation timelines, and lighter reporting requirements. These efforts aim to reduce administrative burdens and create a more enabling environment for smaller companies to grow. Furthermore, the EU aims to enhance single market support for Small Mid-Caps (SMCs), companies larger than SMEs but with fewer than 750 employees and a turnover below €150M, and funding opportunities such as the forthcoming Scaleup Europe fund and the European Competitiveness Fund.

Following this, Olga Solomon from DG SANTE discussed the EU Pharmaceutical Reform with a particular focus on measures targeting SMEs. The reform seeks to establish a simpler and innovation-friendly regulatory framework. Key measures include simplified procedures (e.g. removing renewals, phased reviews, optimised EMA structure), and faster authorisations, including shorter timelines and accelerated pathways for medicines of high public health interest. A digital-by-default approach will mandate electronic submissions and product information, support the use of AI, and facilitate the use of real-world evidence and health data. Future-proof regulation includes regulatory sandboxes for novel therapies, tailored frameworks for cutting-edge technologies, and clarity on interplays between EU legislative frameworks. SMEs will continue to benefit from dedicated support such as fee incentives, scientific advice, and incentive schemes for unmet medical needs, orphan medicines, and antimicrobial resistance (AMR) actions. The Council and the European Parliament, together with the European Commission have been discussing the legislative proposals in the so-called 'trilogues' with a view to reaching an agreement on the final adopted legal texts and the date of application. Beyond the Pharmaceutical Reform, the Critical Medicines Act, the Biotech Act, and the Life Sciences Strategy will also support innovation, competitiveness and SMEs in the pharmaceutical sector.

The session then focused to funding perspectives. Dana Burduja of the European Investment Bank (EIB) outlined the EIB's strategic role as Europe's largest multilateral lender and its €22 billion investments in life sciences and health over the past five years. She highlighted the availability of both equity and debt instruments tailored to the needs of SMEs, particularly through the InvestEU programme. Dana Burduja emphasised the importance of blended finance solutions that combine public and private funding to de-risk early-stage investments and support scale-up.

Complementing this, Orsolya Symmons from the European Innovation Council and SMEs Executive Agency (EISMEA) presented the EIC support tools for SME innovators. The European Innovation Council (EIC) supports high-risk, breakthrough innovations by SMEs through funding and advisory services. Key instruments include Pathfinder (early-stage research), Transition (developing business cases), and Accelerator (market entry and scale-up), offering grants and equity. Additional services include mentoring, global partnerships, and the EIC Community Platform. She highlighted the collaboration with EMA since 2021 focusing on regulatory training and support to help innovators navigate regulatory frameworks.

From the private sector perspective, Sander Slootweg of Invest Europe provided insights into current venture capital trends. He noted that while investor interest in biotech remains strong, regulatory predictability is a key factor influencing investment decisions. Uncertainties related to approval timelines or market access can deter funding, especially for SMEs operating on limited resources.

Bringing an academic and incubator viewpoint, Christel Bergström from Uppsala University shared her experience supporting early-stage life science companies. She highlighted the importance of translational infrastructures, such as laboratory facilities, mentorship programmes, and regulatory

guidance, in helping SMEs progress from concept to clinic. She advocated for stronger links between academia, incubators, and regulatory bodies to ensure that promising innovations are not lost due to insufficient support.

Finally, Virginie Hivert from EURORDIS – Rare Diseases Europe – brought the patient perspective. She underscored the vital role SMEs play in developing treatments for rare conditions and called for continuing the EMA's regulatory and financial support tailored to the unique challenges faced by these companies. She also stressed the importance of early and sustained dialogue between developers, regulators, and patient communities to support the translation of innovation. The future Biotech Act was also highlighted as an important instrument to help address SME barriers such as regulatory complexity, market access, AI and data resources.

3. Review of experience with SME initiative (session 2)

Session 2 of the EMA roundtable focused on the achievements of the SME Regulation over the past two decades, the role of SMEs in pharmaceutical innovation, support to SMEs from the EU regulatory agencies Network and insights from the EMA SME survey. To finalise this session, SMEs shared their experience with the support and incentives received. The session was chaired by Helene Casaert from the EMA SME Office.

Leonor Enes highlighted the key achievements of the EMA's SME regulation over the last years. She presented an overview of the profile of registered SMEs and the increased uptake of regulatory support and fee incentives, as well as initiatives in training, communication and stakeholders' engagement. High figures of registered SMEs and the extensive use of development support tools such as scientific advice, Innovation Task Force meetings and PRIME scheme highlight the innovative profile of SMEs supported by EMA. She also emphasised the importance of strengthening engagement with public research organisations, universities, life-science incubators, to better support academic researchers and SMEs emerging from such organisations. The close and effective cooperation with the European Commission and executive agencies, including the European Innovation Council, was also emphasised in particular for the implementation of the SME definition and the support provided to EU-funded SMEs and academic researchers. An overview of marketing authorisations was also presented noting improved success rates for marketing authorisation applications from SMEs between 2021 and 2025 at 73%, compared to 63% during 2016-2020. Dedicated support provided after scientific advice and in the run-up to the marketing authorisation application was highlighted as an area in which EMA's role is considered particularly important and needs to be strengthened.

Laurence O'Dwyer, co-chair of the EU Innovation Network, outlined the support available to SMEs at national level through the network of local Innovation Offices. These offices serve as first point of contact for innovators and offer guidance on regulatory support available at both National and European levels. He emphasised the importance of the simultaneous scientific advice procedure, which helps developers align with regulatory requirements early and reduce regulatory timelines. In addition, horizon scanning and stakeholder engagement activities to ensure regulators anticipate emerging technologies and adapt frameworks accordingly were highlighted.

Thomas Ballotti, from the EMA SME office, presented the results of the SME survey launched in 2024 to receive feedback from SMEs and stakeholder organisations on the functioning of the SME Regulation. The survey confirmed that the SME Regulation continues to successfully deliver on its intended objectives and remains highly relevant to SMEs. It also highlighted the need to continue raising awareness of the programme and to expand certain services such as regulatory assistance, training and fee incentives. The top three challenges identified by SMEs were the administrative and regulatory burden, access to finance and regulatory fees. Suggested support measures to address these

challenges include regulatory simplification and streamlining, facilitating and expanding access to EU funding programs, and introducing flexible payment modalities.

Representatives from AKIGAI and Vethellas SA, SMEs engaged in the development of human and veterinary medicines, shared their positive experience with the support and guidance provided under the SME programme. They emphasised that obtaining SME status was pivotal in shaping a viable development strategy and securing funding. They highlighted the value of regulatory advice, which enabled them to progress their development programs effectively, while fee incentives covering the entire product life cycle along with assistance with translations of product information were regarded as particularly valuable.

4. Presentations from industry organisations and discussion (session 3)

During the third session industry stakeholders from the veterinary, human health, and MedTech sectors shared feedback on the SME initiative. Participants included Access VetMed, Animal Health Europe, the Association of Veterinary Consultants (AVC), the Association of the European Self-Medication Industry (AESGP), the Alliance for Regenerative Medicines (ARM), the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Pharmaceutical association representing Small to Medium sized Companies in Europe (Europharm SMC) and MedTech & Pharma Platform (MPP).

Industry stakeholders emphasised the crucial role of EMA's SME regulation and the SME Office in supporting innovation and SMEs. Tailored regulatory advice, fee reductions, translation services, and training were highlighted as key measures that have facilitated the development and authorisation of new medicines.

Veterinary medicines industry organisations stressed the importance of SMEs in the sector but highlighted ongoing challenges related to limited resources, smaller markets, and disproportionate regulatory obligations. Pharmacovigilance requirements, lifecycle management, and regulatory fees continue to pose significant hurdles. Incentives and assistance by the EMA SME Office were highly valued particularly assistance with translations, fee deferrals, and regulatory advice which delivered tangible time and cost savings. Veterinary stakeholders called for greater awareness of SME status and associated incentives, dedicated veterinary guidance and training such as a simplified EMA SME User Guide including practical examples, specific guidance on fees and veterinary SME info days. Suggestions were also made on increasing dialogue with industry organisations, easing SME registration with EMA, reviewing the economic relevance of SME criteria thresholds and considering the introduction of a "small mid-cap" category.

Human medicines industry organisations praised the EMA's SME regulation for its pivotal role in de-risking early development through tailored regulatory assistance, Innovation Task Force meetings, scientific advice, PRIME and fee incentives. Raising awareness to these tools and incentives together with training have helped SMEs align development strategies with regulatory expectations and lowered hurdles for applicants with limited regulatory expertise. Despite these successes, awareness and uptake of EMA services remain uneven, particularly among SMEs in the medical devices sector.

Challenges highlighted by human medicines stakeholders included the burden and complexity of EU regulatory frameworks (clinical trials, medical devices and in vitro diagnostics regulations), which disproportionately affect SMEs with limited resources. Additional challenges included planned horizontal initiatives such as the European Commission's Omnibus legislation on EU's sustainability reporting

framework, the introduction of a cost-based EMA fee model, and the lack of incentives for small companies that exceed SME thresholds.

Looking ahead, human medicines industry organisations called for a regulatory ecosystem that is equipped to support emerging technologies such as advanced therapy medicinal products (ATMPs) and digital therapeutics. They highlighted the need for SME-centric horizon scanning and foresight mechanisms to ensure regulatory systems keep pace with innovation emerging from smaller developers. Further proposals included reviewing the SME regulation with respect to SME thresholds, considering the introduction of a "small mid-cap" category for enterprises which may face similar challenges as SMEs, and exploring incentives for highly innovative entities. A suggestion on a coordinated innovation and access helpdesk for SMEs covering multiple regulatory frameworks was also highlighted.

5. Conclusions

The roundtable reaffirmed the relevance and impact of the SME initiative, which was unanimously acknowledged by participants. Over the past two decades, EMA's SME programme has enabled smaller companies advance innovation and support the development and authorisation of new human and veterinary medicines.

Stakeholders identified key areas to further support SMEs: enhancing training and regulatory assistance, improving awareness of available tools and incentives, simplifying administrative processes, and revising SME eligibility criteria. They also highlighted the need for more integrated support structures and enhanced horizon scanning to ensure regulatory systems keep pace with innovation emerging from smaller companies.

EMA remains firmly committed to supporting SMEs and innovation. We will continue to engage closely with stakeholders and partners to shape future actions targeting SMEs, foster innovation and competitiveness, and accelerate access to new therapies for both patients and animals. These efforts will consider the pharmaceutical legislation reform and other EU initiatives, including the Biotech Act, the Critical Medicines Act, the Biotechnology and Biomanufacturing and the Life Sciences strategies.