

Ardena Insight

Empowering Innovation: EMA Support for SMEs Through Scientific Advice and Early Dialogue

The European Medicines Agency (EMA) plays a critical role in supporting micro, small, and medium-sized enterprises (SMEs) across the EU pharmaceutical sector. These companies are vital engines of innovation, especially in areas like rare diseases, advanced therapies, and pediatric medicine. Recognizing the unique challenges SMEs face in bringing medicines to market, the EMA established the SME Office in 2005 to serve as a dedicated support hub. Since then, the SME Office has been instrumental in helping smaller companies navigate the complex regulatory landscape.

Scientific advice is one of the most powerful tools available to SMEs during drug development. It enables early dialogue with EMA experts on critical aspects of a development program, such as trial design, manufacturing, and regulatory requirements. The goal is to reduce uncertainty, ensure compliance with EU standards, and increase the likelihood of a successful marketing authorization application (MAA).

To make this service accessible, SMEs benefit from a 90% fee reduction for scientific advice. For orphan-designated products, the fee may be waived entirely. This incentive dramatically lowers the cost of regulatory engagement and allows SMEs to receive tailored, high-quality input on their programs—especially during pivotal development stages.

The Innovation Task Force (ITF) is an EMA-led forum for early, informal dialogue on emerging technologies and novel therapeutic concepts. SMEs can request ITF briefing meetings to explore regulatory opportunities and challenges associated with cutting-edge modalities such as gene therapies, digital therapeutics, or combination products.

These early interactions are particularly valuable for identifying potential scientific and regulatory hurdles well in advance, helping SMEs align their innovation with evolving regulatory expectations. While ITF meetings are non-binding, they serve as a springboard for later formal interactions, such as scientific advice or PRIME eligibility.

Under EU regulations, companies developing medicines for adult use may also need to investigate their use in children through a Paediatric Investigation Plan (PIP), unless a waiver or deferral is granted. PIPs are reviewed by the Paediatric Committee (PDCO) and must be agreed upon early in development. SMEs benefit from fee waivers for PIP-related procedures and can receive extended market exclusivity (e.g., a six-month extension of the supplementary protection certificate).

These incentives help reduce financial risk while promoting the development of pediatric medicines—a key public health objective of the EMA.

Since its creation in 2005, the SME Office has championed a collaborative, science-driven approach to regulatory development. Tools like scientific advice, ITF meetings, and PIP support help SMEs transform innovative ideas into safe, effective, and approved medicines. This sustained regulatory dialogue enables small companies to compete on a level playing field with larger industry players.

Ardena can support your team in developing a robust regulatory strategy and maximizing the value of EMA engagement. We offer end-to-end support for scientific advice meetings, including preparation of briefing documents, regulatory gap assessments, and representation during meetings with authorities. With Ardena as your partner, you can approach EMA with confidence and clarity—paving the way for successful product development.