

## EAA Fall Convention

### *EU HTA – Procedural Insights & First Learnings*

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Université Paris Cité & Virtual

#### Impulse Presentation

##### **Speaker name**

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##### **Title of the Talk**

*European Medicines Agency's support to SMEs*

##### **Abstract**

Small and medium-sized enterprises (SMEs) are vital drivers of innovation in the pharmaceutical sector. Recognising the unique challenges these companies face in developing and bringing medicinal products to market, the European Union introduced specific provisions through Commission Regulation (EC) No 2049/2005. This regulation establishes measures to promote innovation and support the development of new medicines by SMEs, including the creation of the SME Office within the European Medicines Agency (EMA), which is specifically designed to address the needs of smaller companies.

The SME Office serves as a central point of contact for micro, small, and medium-sized biopharmaceutical enterprises involved in the development and marketing of medicines. It offers a range of support services, including regulatory and administrative guidance and assistance, financial incentives, and platforms for early dialogue. A key function of the Office is to assess eligibility and grant SME status—an essential prerequisite for accessing tailored support measures. Once granted, SME status entitles companies to significant benefits, such as fee reductions or waivers for scientific advice and inspections, as well as deferrals for marketing authorisation application fees. These incentives are particularly beneficial for smaller companies that often operate with limited financial resources.

In addition to financial incentives, the SME Office provides comprehensive regulatory and administrative assistance throughout the entire product development lifecycle. This includes support in preparing regulatory submissions, accessing scientific advice, and navigating complex regulatory and administrative requirements—all with the aim of increasing predictability and the likelihood of regulatory success. The Office also facilitates

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knowledge-sharing and capacity-building by offering targeted training sessions, webinars, and educational materials, and by engaging with a broad network of partners and stakeholders that support SMEs in the pharmaceutical sector.

Through these initiatives, the EMA SME Office plays a crucial role in fostering pharmaceutical innovation by equipping SMEs with the guidance, tools, and incentives necessary to successfully bring new therapies to market.