

EFPIA SME Group's position paper on EC SME Strategy For a sustainable and digital Europe

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the innovative pharmaceutical industry operating in Europe, since January 2020 also including biopharmaceutical Small- and Medium-sized Enterprises (SME's).

The EFPIA SME Group welcome the European Commission SME Strategy published on 10 March 2020 as an opportunity to strengthen the business environment for Small and Medium-sized Enterprises active in medical R&D in Europe, and thereby the entire European R&D eco-system.

EFPIA SME Members appreciate the Commission's support to transitioning to sustainability and digitalization, as well as reducing regulatory burden and improving market access. In EFPIA's response to the Commission Industrial Strategy, EFPIA emphasises the importance of driving innovation in Europe with shared solutions on access and availability. These solutions include an IP framework that protects investment in medical research, a regulatory framework that is stable, fast, effective and globally competitive, and faster, more equitable access to new treatments for patients across Europe. These solutions are even more important for biopharmaceutical SMEs operating in Europe.

EFPIA SME Members have particularly been interested in the proposals related to improving access to financing. References to new ways of risk-sharing with the private sector to boost the size of venture capital funds or an SME IPO Fund are very well received. The initiative InvestEU would particularly apply to our high risk and innovative biopharmaceutical sector.

In Europe, running Phase III clinical trials and launching a product on the market is very expensive and requires raising several hundreds of millions of euros through private funds and public markets that are fragmented. Compared to the US, there are no large specialised funds in Europe available to support such a process. Additionally, the absence of a public market with the depth of the Nasdaq in the US renders IPO much more challenging. This situation pushes many European innovative biotech SMEs to move to the US in order to find funding.

The Commission's reference to InvestEU that will pool funding from the EU, Member States and the private sector - such as business angels, family offices, venture capital funds, pension funds and insurance companies - is very much in line with what EFPIA SME Members have identified as key to bring back to Europe innovative biopharmaceutical SMEs that are currently looking for funding in other regions of the world. We would look forward to further discussing this tool with the European Commission to ensure that it is fully adapted to the needs of the European biopharmaceutical sector for the benefit of biopharmaceutical SMEs.

EFPIA SME Members have also noticed the reference to the SME definition and that the European Commission will further assess specific issues linked to complex ownership structures. European biopharmaceutical SMEs that belong to Family Offices are part of these complex ownership structures and consequently do not comply with the SME definition. We would welcome a dialogue to explain to the Commission this specificity of the biopharmaceutical environment to help improve the situation for biopharmaceutical SMEs operating in Europe.