SPC waiver risks downgrading the EU as a hub for health innovation

PRESS RELEASE

28 May 2018, Brussels: As an association that has manufacturers of both originator and biosimilar medicines as members, EuropaBio strongly doubts that the promises of today's Commission proposal outweigh the risks of losing investment in new medicines. *"Today's proposal can only weaken the attractiveness of the EU as a hub for biopharmaceutical innovation. The approach of taking incentives away from one part of the biopharmaceutical industry to give to another part of the same industry is the wrong way to serve patients and foster innovation in Europe. Instead, solutions for enabling the entire EU biopharma industry to meet the needs of EU patients should have been explored."*, commented John Brennan, Secretary General of EuropaBio, on the European Commission's proposal for a waiver of the rights of holders of Supplementary Protection Certificates for innovative medicines.

Costly and highly uncertain investment decisions into R&D in health can only be taken in the presence of carefully balanced, reliable and enforceable incentives and safeguards against failure and long-term lack of profitability. "European developers of tomorrow's cures are mainly small businesses. In today's world, where these small biotech businesses depend on investor funding from outside Europe, this proposal sends the wrong signal and jeopardises progress and innovation in health – where are the safeguards to make sure that does not happen?", added Mr. Brennan.

EuropaBio's early analysis of the proposal finds that rather than promoting growth and jobs in the entire sector, an SPC waiver would simply shift value and jobs from the originator part of the biopharmaceutical industry to the biosimilar and generic part of the same EU health industry with the only result being a negative net impact on innovation for patients. The proposal also seems absent of robust safeguards in this regard. EuropaBio stands ready to contribute expertise and experience for alleviating the foreseeable damage to the finely balanced EU biopharma innovation ecosystem.

Additional information:

- With yearly R&D investments in the range of €30 billion, the EU biopharmaceutical industry is the EU's most research-intense sector, providing around 700 000 highly skilled jobs for the EU citizens.
- SMEs develop 27% of all new medicines and up to 61% of innovative orphan medicinal products. Strong protection for SMEs' IP rights is vital for their access to venture capital and, hence, for their survival and business sustainability.

- See also:
    1. Europe Economics reviews EC commissioned CRA report on SPCs for manufacturing purposes
    2. From Patent to Patient: The importance of IP rewards and incentives (EuropaBio survey findings)

ENDS

Media contact

Cosmin Popa, EuropaBio Communications and National Associations Manager

Email: c.popa@europabio.org / Telephone: +32 2 739 11 73 / Mobile: +32 499 906 129

About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents 75 corporate members and 17 national biotechnology associations and bioregions.

Read more about our work at www.europabio.org.