



MARCH 2026

# POSITION PAPER

## THE BIOTECH ACT

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### **Introduction**

AIM, the International Association for Mutual Benefit Societies representing statutory and complementary health insurance funds and mutuels in 16 European countries welcomes the Biotech Act proposed by the European Commission on December 16th, 2025.

Europe's competitiveness in biotechnology harnessing the excellence and quality of research and industry is of utmost importance. At the same time, our members based on solidarity, not for profit and democracy underline the need to put the improvement of patient's lives in the centre of the ambition of the European Commission in this respect. The patient should be the beneficiary of the innovation and should enjoy the highest quality and safety standards. Biotechnology should thus be affordable, available and accessible for all without inequalities.

In this position, AIM would like to draw the attention to the following points of attention for our members:

### **Health insurance funds and mutuels are important actors**

AIM welcomes that HTA bodies are participating in the foresight panel to coordinate horizontally and identify emerging technologies early. AIM also subscribes to strengthen the evidence base for health technology and streamlining the Clinical Trials Regulation. For AIM, early access to and affordability of new technologies for patients is key. In this respect, incentivizing the development and faster access of biosimilars is a positive aspect of the Biotech Act. High quality, effective and efficient therapies help health insurance funds and mutuels to steer their budgets towards improved care.

### **What needs to be changed from our point of view?**

#### **Innovation should go hand in hand with value**

AIM welcomes the ambition for high impact strategic projects as laid out in Art. 4. However, for us the improvement of the (quality of) life of patients as well as affordability of new therapies is essential. We therefore propose to change Art. 4 adding a criterion that requires these projects to demonstrate a clear potential for improving the (quality of) life of patients as well as the sustainability and efficiency of healthcare systems.



## **Extending the supplementary protection certificate (SPC) is not an option**

As mentioned in the introduction, for solidarity based and not for profit health insurance funds and mutuals, the improvement of people's health, effective and efficient care should be prioritized before competitiveness. Competitiveness is not an end in itself, but serves to achieve certain objectives, such as improving people's health and providing effective and efficient care. In this respect, we are against the extension of the SPC as laid down in Art. 27. This is clearly in contrast to our goal of affordable healthcare as it would reduce the positive effects of competition by generic manufacturers.

With healthcare budgets under constant pressure for raising costs, especially for new therapies and pharmaceuticals, extending the protection certificate is therefore not acceptable to AIM. We therefore call for removing this Art.

## **Health insurance funds and mutuals need robust data quality**



Reducing clinical data for biosimilar approval cannot come at the cost of robust, analytical and other non-clinical evidence. We therefore propose to change Art. 28 to include that the reduction of clinical data is balanced by 'robust analytical and other non-clinical evidence'.

The Act heavily focuses on shortening the clinical trial authorisation timelines (from 106 to 75 days) and simplifying requirements for 'minimal-intervention' trials. While AIM favours fast access, this has not to come at the cost of less data quality and, ultimately, product quality. According to us, robust and comparative data are needed to determine the relative effectiveness and value for money of the products. We therefore suggest changing Art. 58 by including a 'HTA readiness' check within the clinical trial application process to ensure that data generated meet the evidence requirements for reimbursement decisions or discussions.

## **Avoid any evidence gaps with regulatory sandboxes**

The article establishes several regulatory sandboxes. AIM members fear that those controlled, experimental environments cannot be generalizable to real-world populations or standard clinical practice thus leading to 'evidence gaps' when the product moves from the sandbox to a national reimbursement application. AIM therefore proposes to change Art. 40.6 to be amended and make the consultation with the Coordination Group on Health Technology Assessment (HTACG) mandatory during the development of sandbox plans in order to ensure the generation of useful data for value assessment. AIM and its members stand ready to discuss this position.

### **FURTHER INFORMATION**

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## Who are we?

### International Association of Mutual Benefit Societies

The International Association of Mutual Benefit Societies (AIM) is a global network for equitable health and social care, which serves as the international umbrella organisation for federations of health mutuals and statutory and complementary health insurance bodies.

The work of our members is based on solidarity, not-for-profit work and democracy across Europe, Latin America, Africa, and the Middle East. We advocate for equal access to health and care, fair pricing of medicines, a digitalisation that serves the insured, the integration of health in all policies and a stronger focus on prevention.

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