



BIO DEUTSCHLAND

Joint Statement on the Innovative Medicines Initiative

The Innovative Medicines Joint Technology Initiative (IMI) was launched in May 2007. From the beginning, significant stakeholder groups have expressed concerns about IMI's intellectual property rights policy and its funding model. These concerns have been repeated on several occasions and have been transmitted to the IMI Member States Group, the IMI Joint Undertaking (JU) Governing Board and the European Commission.

The IMI JU is currently reviewing its intellectual property policy and the funding rules for reimbursement of indirect costs. A group of IMI stakeholders has decided to publish this joint statement to provide useful input in this review process and ensure that long-standing concerns from all key stakeholders are addressed.

The IMI JU has already launched two calls for proposals and is preparing a third call. Participation in the first two calls has been well below potential, because many organisations – SMEs, research organisations and universities – have not participated fully as a result of concerns regarding the complex and potentially un-balanced IMI IP policy and unattractive funding model. The programme is unlikely to achieve its objectives if participation remains sub-optimal.

Stakeholders wish to see **IMI's IP policy** revised in order to provide for:

- reasonable definition of research use and of access rights for third parties;
- less extensive access rights for participants and affiliated entities worldwide, or at least better control of access rights by the owner;

- fair conditions for access (time limit, request in writing, fair and reasonable terms rather than royalty free);
- and more balanced and reasonable conditions for licensing, assignment and other disposal of own assets, following the FP7 model (II.26.3 IMI GA).

These central issues have also been identified by the IMI IP Working Group but a resolution is still pending.

With the deadline for the third call rapidly approaching, it is crucial that real improvements are introduced as a matter of urgency.

The **IMI funding model** needs to be sufficiently competitive to attract the best players and to allow SMEs to engage effectively in large numbers. The recent report by the JTIs' Sherpa Group¹ recognises stakeholder concerns and points the way forward. It recommends that "funding rates [...] should be set at levels comparable to those of the Framework Programme"². The Sherpa Group has also recommended that "JTIs should implement measures to more effectively engage the SME community"³.

IMI funding rules should be modelled on FP7 funding rules and the starting point for calculating funding rates should be coverage of the full costs of research. The current 20% cap on the reimbursement of indirect research costs ignores economic reality and must be lifted as a matter of urgency.

The undersigned stakeholder organisations believe that the necessary reforms must be implemented in time for the third IMI call for proposals. This is essential if IMI is to achieve its objectives of fostering long-lasting and fruitful collaborations between research organisations, SMEs, universities and pharmaceutical companies⁴ and if we are serious about creating biomedical R&D leadership in Europe to benefit patients and society⁵.

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¹ *Designing together the ideal house for "public-private" partnerships in European research*, JTI's Sherpa Group, January 2010 - http://ftp.cordis.europa.eu/pub/fp7/docs/jti/jti-sherpas-report-2010_en.pdf

² Cf. Recommendation 3.2

³ Recommendation 2.6

⁴ SEC(2007)568 - "Companies small and large, regulators, governmental institutions, academics and patients need to come together to share resources and expertise to address the challenges of drug discovery and development." - http://imi.europa.eu/docs/comm_pdf_sec_2007_0568_1_en_documentdetravail_en.pdf

⁵ IMI vision: "Creating Biomedical Research & Development leadership for Europe to benefit patients and society" - <http://www.imi-europe.org/Pages/topic.aspx?Item=9&ListId=DA41E506-DF1A-46A3-A541-548CE8F0D9B5>

Notes to Editors:

EARTO

EARTO is the **European trade association** of the research and technology organisations (**RTOs**), a non-profit organisation founded in 1999. **EARTO groups over 350 RTOs**, with a combined staff of 150,000, an annual turnover of €15 Billion, special equipment and facilities to a value of many € billions and more than 100,000 customers from the public and private sectors annually.

<http://www.earto.eu>

EUA

The **European University Association (EUA)** represents and supports **higher education institutions** with approximately 850 members in 46 countries. Members of EUA are European universities involved in teaching and research, national associations of rectors and other associations and networks active in higher education and research.

<http://www.eua.be/Home.aspx>

Helmholtz Association

The **Helmholtz Association** contributes to solving major challenges facing society, science and industry with top scientific achievements in six research areas: Energy, Earth and Environment, Health, Key Technologies, Structure of Matter, Transport and Space. With 30,000 employees in **16 research centres** and an annual budget of approximately 3 billion euros, the Helmholtz Association is **Germany's largest scientific organisation**.

<http://www.helmholtz.de/en/>

FlandersBio

FlandersBio is the **umbrella organisation** for the **life sciences and biotechnology sector** in Flanders. FlandersBio represents over 210 organisations, most of which are **biotech SMEs**, but also research organisations, service and technology providers.

<http://flandersbio.be/>

BIO Deutschland

BIO Deutschland is the voice of the **German biotechnology industry**. Based in Berlin, BIO Deutschland has more than 250 members, including **large and small companies, BioRegions** and **sector service providers**. BIO Deutschland has set itself the target of supporting and promoting the development of an innovative economic sector based on modern biosciences.

<http://www.biodeutschland.org/>

VIB

VIB is a **non-profit research institute** in the **life sciences** in **Flanders, Belgium**. About 1200 scientists conduct strategic basic research on the molecular mechanisms that are responsible for the functioning of the human body, plants, and micro-organisms. Through a partnership with four Flemish universities⁶ and a solid funding program, VIB unites the forces of 72 research groups in a single institute. Through its technology transfer activities, VIB strives to convert the research results into products for the benefit of consumers and patients.

<http://www.vib.be/VIB/EN/>

SwedenBIO

SwedenBIO is the **national Life Science Industry Organization in Sweden**. The main objective is to improve and maintain industry conditions which will support prosperous growth and business development among our, today, **190 member companies**. Our members are active in all sectors ranging from R&D, biotech, medtech to pharmaceuticals, diagnostics and biotech tools to service providers as CROs.

<http://www.swedenbio.com/>

Bio.be

Bio.be is the **Belgian biotechnology industry organisation**. Bio.be represents the companies and professionals involved in research, development, testing, production or marketing of biotechnology applications, as well as those servicing the biotechnology community.

<http://www.bio.be/>

Leibniz Association

The Gottfried Wilhelm Leibniz Scientific Community, known as the **Leibniz Association**, is the **umbrella organisation for 86 institutions** conducting research, providing scientific infrastructure or performing research-based services for the public, policy makers, academia and business. Some 7,100 scientists and scholars work in the humanities and social sciences, economics, spatial and life sciences as well as in mathematics, the natural and engineering sciences and in environmental research. Altogether, ca. 16,000 people are employed at Leibniz Institutes, which have an annual budget of 1,3 billion euro.

<http://www.leibniz-gemeinschaft.de/>

⁶ Ghent University, the Katholieke Universiteit Leuven, the University of Antwerp, and the Vrije Universiteit Brussel