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Committee on the Environment, Public Health and Food Safety

2007/0089(CNS)

10.10.2007

OPINION

of the Committee on the Environment, Public Health and Food Safety

for the Committee on Industry, Research and Energy

on the proposal for a Council regulation setting up the Innovative Medicines Initiative Joint Undertaking
(COM(2007)0241 - C6-0171/2007 - 2007/0089(CNS))

Draftswoman: Dagmar Roth-Behrendt

SHORT JUSTIFICATION

Background
The Innovative Medicines Initiative (IMI) is one of six so called "Joint Technology Initiatives" introduced by the Specific Programme "Cooperation" of the 7th Framework Programme. It is a novel kind of pan-European Public Private Partnership between universities, hospitals, public authorities, patient organisations, clinical centres and pharmaceutical companies with the aim to boosting biomedical research and the development of new therapies.

The IMI will create partnerships through open calls for tender in accordance with a permanently updated Research Agenda. The main focus will be on the pre-competitive sector of pharmaceutical research, thus tools to make early and reliable predictions on the safety and efficiency of medicine candidates in order to deliver potential benefits faster to patients and with greater certainty about the use of therapies. In addition, the IMI will focus research on priority diseases like cancer or Alzheimer, set out by the Research Agenda and foster the collaboration between private and public sectors.

The total budget will be € 2 billion for the period 2007-2013. The contribution from the Community will be € 1 billion. This public funding will be matched by equal contributions from research based pharmaceutical companies, in form of staff, laboratory equipment, clinical research etc.

Community funding will go exclusively to SMEs, non-profit organisations, academia, authorities, clinical centres or patient organisations - not to big companies.

Evaluation
The draftsman warmly welcomes IMI Joint Undertaking which will speed up the development of innovative medicines that reach patients faster and are better fitted to their needs. The Initiative will also result in less risk through human clinical trials.

The scientific and technological progress combined with better knowledge of the human genome allows the development of entirely new approaches to battle diseases. Future medicines and therapies will be more precisely targeted to individual patients and thus improve their living conditions considerably. We know today that there is no single cure for a certain disease - the right therapy rather depends on a multitude of factors like gender, tolerability or specific genetic characteristics. Europe urgently needs more investment into research and development in this field in order to deliver potential benefits quickly to patients.

This is why enhanced public funding in pre-competitive research activities is particularly justified and will entail more private funding on the medium term and make Europe more attractive for talented scientist. It has to be recognised that the development of a new therapy is a very costly and unpredictable undertaking. Only a small part of medicines candidates reaches the stage of a marketing authorisation. The vast majority of research activities ends due to safety or efficiency concerns after hundreds of millions of Euros have been spend during the development process. At the same time, the investment into biopharmaceutical research in Europe is loosing pace with other parts of the world like the US or Japan.

Therefore, the IMI starts from the right point by using public and private money to boost large

scale pan-European research in order to identify at the earliest possible stage whether a medicine candidate has the potential top become a safe and effective cure and to foster the collaboration between industry, academia and the non-profit sector for the benefit of the whole society.

IMI-projects will ensure that the substantial research needed to develop and validate new tools for drug discovery and development is well coordinated and will avoid the duplication of work. Through the cooperation with big companies small scale research centres will also get the chance to get their ideas up and running.

The draftsman proposes a few amendments to the Commission's proposal, mainly aiming at ensuring an up-to date research agenda and an effective dissemination of the results to the public and private sector.

In addition, improved transparency through a closer involvement of the European Parliament should be ensured by appointing independent EP representatives to the IMI Board.

Whilst the proposal gives a prominent role to one research based pharmaceutical association, it should be noted that there are also research activities with known substances, e.g. in the area of herbal or non-prescription medicines. The participation of these companies and the relevant trade association in the IMI JU must be possible.

Finally, it should be emphasised that beside evident benefits for Europe's competitiveness and diminished risk through human clinical trials, IMI projects will as well have a positive effect on the need for animal tests. Unnecessary tests will be avoided if a potential failure of a medicine candidate is recognised at an early stage and new tools in the drug development process will mostly not rely on animal tests but on new in-vitro techniques or computer based technologies.

AMENDMENTS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on Industry, Research and Energy, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament
Amendment 1 Recital 11	
(11) The Joint Technology Initiative on "Innovative Medicines" should propose a coordinated approach to overcome identified research bottlenecks in the drug development process, and to support 'pre-competitive pharmaceutical research and development', in order to accelerate the development of safe and more effective medicines for patients. In the present context 'pre-competitive pharmaceutical research and development' should be understood as research on the tools and methodologies used in the drug development process.	(11) The Joint Technology Initiative on "Innovative Medicines" should propose a coordinated approach to overcome identified research bottlenecks in the drug development process, and to support 'pre-competitive pharmaceutical research and development', in order to accelerate the development of safe and more effective medicines for patients. In the present context 'pre-competitive pharmaceutical research and development' should be understood as research on the tools and methodologies used in the drug development process. ***Intellectual property originating from an Innovative Medicines Initiative (IMI) project should be licensed to third parties on fair and reasonable terms.***
Justification	
It should be clarified that the intellectual property necessary to make use of the research tools developed by the partners of an IMI project, will be made available to third parties on fair and reasonable terms.	
Amendment 2 Article 7, point (g)	
(g) qualified non-profit patients organisations.	(g) qualified non-profit patients organisations ***according to criteria to be established and defined by the Commission.***

[1] Not yet published in OJ.

Justification

There is a clear need for the Commission to establish certain criteria for non-profit patients organisations in terms of transparency and accountability to qualify for this particular funding.

Amendment 3
Annex, Article 2, paragraph 2, point (c)

(c) to make any necessary adjustments to the Research Agenda of the Joint Technology Initiative on "Innovative Medicines" in light of scientific developments occurring during its implementation;	(c) to ***regularly review and*** make any necessary adjustments to the Research Agenda of the Joint Technology Initiative on "Innovative Medicines" in light of scientific developments occurring during its implementation ***and in order to ensure that the health care priorities and the needs of patients are adequately addressed in Europe***;

Justification

The Research Agenda should be systematically reviewed in order to ensure that scientific progress and the benefit for patients in Europe are permanently taken into account.

Amendment 4
Annex, Article 5, paragraph 1, point (f a) (new)

	(fa) the European Parliament shall appoint two independent representatives and two substitutes to the Board.

Justification

Given the role of the European Parliament as part of the Budget Authority, it should be represented in the Board.

Amendment 5
Annex, Article 6, paragraph 2, point (e), indent 6

- prepare the annual budget proposal, including the staff establishment plan;	- prepare the annual budget proposal, including the staff establishment plan, ***after consultation with the Scientific Committee and the Member States Group***;

Justification

The Executive Director should consult other relevant bodies of the IMI before submitting the annual budget proposal to the Board.

Amendment 6
Annex, Article 6, paragraph 7, point (i)

(i) call the annual meeting of the Stakeholder Forum, to ensure openness and transparency of the activities of the IMI Joint Undertaking with its stakeholders;	(i) call the annual meeting of the Stakeholder Forum***, an open meeting for relevant organisations with an interest in biomedical research to provide feedback on IMI activities***, to ensure openness and transparency of the activities of the IMI Joint Undertaking with its stakeholders;

Justification

Clarification of the nature of the annual stakeholder meeting which aims at ensuring openness and transparency of the activities of the IMI Joint Undertaking with its stakeholders.

Amendment 7
Annex, Article 13, paragraph 2, subparagraph 1 a (new)

	The Executive Director shall present the annual activity report to the European Parliament.

Justification

As part of a regular dialogue with the European Parliament the Executive Director should present the Annual Activity Report to the European Parliament.

PROCEDURE

Title	Establishment of the Innovative Medicines Initiative Joint Undertaking
References	COM(2007)0241 - C6-0171/2007 - 2007/0089(CNS)
Committee responsible	ITRE
Opinion by Date announced in plenary	ENVI 19.6.2007
Drafts(wo)man Date appointed	Dagmar Roth-Behrendt 19.9.2007
Date adopted	8.10.2007
Result of final vote	+: 25 –: 0 0: 2
Members present for the final vote	Pilar Ayuso, Irena Belohorská, Johannes Blokland, John Bowis, Frieda Brepoels, Martin Callanan, Dorette Corbey, Edite Estrela, Jill Evans, Karl-Heinz Florenz, Satu Hassi, Dan Jørgensen, Christa Klaß, Aldis Kušķis, Jules Maaten, Miroslav Ouzký, Vittorio Prodi, Dagmar Roth-Behrendt, Kathy Sinnott, María Sornosa Martínez, Antonios Trakatellis, Thomas Ulmer, Anja Weisgerber, Glenis Willmott
Substitute(s) present for the final vote	Iles Braghetto, Christofer Fjellner, Radu Ţîrle