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REPORT

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

Committee on Industry, Research and Energy

Rapporteur: Françoise Grossetête

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- *** Assent procedure
*majority of Parliament's component Members except in cases
covered by Articles 105, 107, 161 and 300 of the EC Treaty and
Article 7 of the EU Treaty*
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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

(Consultation procedure)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2007)0241),
 - having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities¹ (Financial Regulation), and in particular Article 185 thereof,
 - having regard to the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management²(IIA), and in particular Point 47 thereof,
 - having regard to Articles 171 and 172 of the EC Treaty, pursuant to which the Council consulted Parliament (C6-0171/2007),
 - having regard to Rule 51 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy and the opinions of the Committee on Budgets and the Committee on the Environment, Public Health and Food Safety (A6-0479/2007),
1. Approves the Commission proposal as amended;
 2. Considers that the reference amount indicated in the legislative proposal must be compatible with the ceiling of heading 1a of the current multiannual financial framework 2007-2013 and with the provisions of Point 47 of the Interinstitutional Agreement (IIA) of 17 May 2006; notes that any financing beyond 2013 will be evaluated in the context of the negotiations for the next financial framework;
 3. Recalls that the opinion delivered by the Committee on Budgets does not pre-empt the outcome of the procedure laid down in Point 47 of the IIA of 17 May 2006 which applies to the setting up of the Innovative Medicines Initiative Joint Undertaking;
 4. Calls on the Commission to alter its proposal accordingly, pursuant to Article 250(2) of the EC Treaty;
 5. Calls on the Council to notify Parliament if it intends to depart from the text approved by

¹ OJ L 248, 16.9.2002, p. 1. Regulation as amended by Regulation (EC, Euratom) No 1995/2006 (OJ L 390, 30.12.2006, p. 1).

² OJ C 139, 14.6.2006, p. 1.

Parliament;

6. Asks the Council to consult Parliament again if it intends to amend the Commission proposal substantially;
7. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission

Amendments by Parliament

Amendment 1
Recital 10

(10) The objective of the Joint Technology Initiative on "Innovative Medicines" should be to foster collaboration between all stakeholders such as industry, public authorities (including regulators), organisations of patients, academia and clinical centres. The Joint Technology Initiative on "Innovative Medicines" should define a commonly agreed research agenda (hereinafter referred to as "Research Agenda"), closely following the recommendations of the Strategic Research Agenda developed by the European Technology Platform on "Innovative Medicines".

(10) The objective of the Joint Technology Initiative on "Innovative Medicines" should be to foster collaboration between all stakeholders such as industry, ***including small and medium-sized enterprises (SMEs)***, public authorities (including regulators), organisations of patients, academia and clinical centres. The Joint Technology Initiative on "Innovative Medicines" should define a commonly agreed research agenda (hereinafter referred to as "Research Agenda"), closely following the recommendations of the Strategic Research Agenda developed by the European Technology Platform on "Innovative Medicines".

Justification

SMEs should also be stakeholders in the IMI.

Amendment 2
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

(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.

context 'pre-competitive pharmaceutical research and development' should be understood as research *into* the tools and methodologies used in the drug development process ***generally, rather than in the process of developing any particular drug. Intellectual property arising under a Joint Technology Initiative on "Innovative Medicines" project should be licensed to third parties on fair and reasonable terms.***

Justification

The IMI is intended to identify 'research bottlenecks', and should not be used as a means of funding the development of particular drugs.

Amendment 3
Recital 13 a (new)

(13a) In pursuit of the objectives of the Specific Programme Cooperation, the IMI Joint Undertaking should make provision for boosting SME participation, inter alia by improving administrative procedures, taking their requirements more fully into account and deploying support measures.

Justification

SMEs do not always have all the logistical resources required for certain tasks. The IMI should not impose excessively onerous administrative formalities on small and medium-sized firms, which are often obliged to contract out certain activities which they lack the structural capacity to carry out themselves.

Amendment 4
Recital 13 b (new)

(13b) In pursuit of the objectives of Council Decision 2006/974/EC of 19 December 2006 on the Specific Programme: Capacities implementing the Seventh Framework Programme of the European Community for research, technological development and

demonstration activities (2007 to 2013)¹, the IMI Joint Undertaking should be attuned to investment in research for the benefit of SMEs and to enhancing their capacity for innovation and their ability to exploit the results of research.

¹OJ L 400, 30.12.2009, p. 299.

Amendment 5
Recital 14

(14) The IMI Joint Undertaking should be set up for an initial period ending on **31 December 2017** to ensure the appropriate management of research activities initiated but not concluded during the Seventh Framework Programme (2007-2013).

(14) The IMI Joint Undertaking should be set up for an initial period ending on **31 December 2013**. To ensure the appropriate management of research activities initiated but not concluded during the Seventh Framework Programme (2007-2013), **work in progress should continue until 31 December 2017, if necessary**.

Justification

The duration of the IMI Joint Undertaking must be modelled on that of the Seventh Framework Programme, because it is partly funded by it. An additional period may nonetheless be granted in order to complete work in progress.

Amendment 6
Recital 16

(16) The IMI Joint Undertaking should be a body set up by the Communities and discharge for the implementation of its budget should be given by the European Parliament, **on the recommendation of the Council, taking however into account the specificities resulting from the nature of JTIs as public-private partnerships and in particular from the private sector contribution to the budget**.

(16) The IMI Joint Undertaking should be a body set up by the Communities and discharge for the implementation of its budget should be given by the European Parliament, **taking into account a recommendation from the Council**.

Justification

By analogy with the conclusions of the trilogue of 7 March 2007 on the Joint Undertaking for

ITER, the European Parliament should be given full and unconditional responsibility for the discharge of the implementation of the budget of the IMI JU.

Amendment 7
Recital 17

(17) Founding members of the IMI Joint Undertaking **should** be the European Community and EFPIA.

(17) *The* founding members of the IMI Joint Undertaking **are** the European Community and EFPIA.

Justification

Clarification.

Amendment 8
Recital 26

(26) The research based pharmaceutical companies that are full members of EFPIA activities shall not be eligible to receive support from the IMI Joint Undertaking.

(26) The research based pharmaceutical companies that are full members of EFPIA activities shall not be eligible to receive **direct or indirect** support from the IMI Joint Undertaking.

Justification

To avoid confusion, the nature of the support precluded should be clarified.

Amendment 9
Recital 27

(27) The IMI Joint Undertaking should have, subject to prior consultation with the Commission, a distinct Financial Regulation based on the principles of the framework financial regulation which takes into account its specific operating needs arising, in particular, from the need to combine Community and private funding to support research and development activities in an efficient and timely manner.

(27) The financial rules applicable to the IMI Joint Undertaking should not depart from Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities¹, unless their specific operating needs so require, in particular the need to combine Community and private funding to support research and

development activities in an efficient and timely manner. ***The prior consent of the Commission is required for the adoption of any rules which depart from Regulation (EC, Euratom) No 2343/2002. The budgetary authority should be informed of such derogations.***

¹ OJ L 357, 31.12.2002, p. 72. Corrigendum in OJ L 2, 7.1.2003, p. 39.

Justification

Derogations from Regulation No 2343/2002 should be kept to an absolute minimum. The Joint Undertaking has to prove beyond any doubt that such a derogation is the only way to guarantee its proper functioning within the limits of its founding regulation.

Amendment 10 Recital 28

(28) The ***need*** to ensure stable employment conditions and equal treatment of staff, and ***in order to attract*** specialised scientific and technical staff of the highest calibre, ***requires the application of the Staff Regulations of Officials of the European Communities and the Conditions of Employment of Other Servants of the European Communities, ("the Staff Regulation") to all staff recruited by the IMI Joint Undertaking.***

(28) The ***requirement*** to ensure stable employment conditions and equal treatment of staff, and ***the need for*** specialised scientific and technical staff of the highest calibre, ***call for a degree of flexibility in the recruitment of staff for the IMI Joint Undertaking. The partnership should be balanced and each of the Founding Members should be in a position to recruit staff. The Commission should thus be free to second as many officials as it regards necessary to the Joint Undertaking and the latter to recruit staff on a contractual basis in accordance with the employment law in force in the state where it has its seat.***

Justification

Preference should be given to a flexible, light-touch approach. The partnership should be balanced, and each founding member (Commission/EFPIA) should be in a position to recruit staff.

Amendment 11 Recital 33

(33) The IMI Joint Undertaking should be

(33) The IMI Joint Undertaking should be

established in Brussels, Belgium. A host agreement should be concluded between the IMI Joint Undertaking and Belgium concerning office accommodation, privileges and immunities and other support to be provided by Belgium to the IMI Joint Undertaking.

established in Brussels, Belgium. A host agreement should be concluded between the IMI Joint Undertaking and Belgium concerning ***the assistance with regard to*** office accommodation, privileges and immunities and other support to be provided by Belgium to the IMI Joint Undertaking.

Justification

It should be clearly stipulated that the host country of any agency or similar Community body is expected to provide financial and all other assistance necessary to facilitate the setting-up and running of the Community body.

Amendment 12
Article 1, paragraph 1

1. For the implementation of the Joint Technology Initiative on Innovative Medicines, a Joint Undertaking is hereby set up for a period ending on ***31 December 2017*** (hereinafter referred to as "IMI Joint Undertaking"). ***This period may be extended by the Council.***

1. For the implementation of the Joint Technology Initiative on Innovative Medicines, a Joint Undertaking is hereby set up for a period ending on ***31 December 2013*** (hereinafter referred to as "IMI Joint Undertaking"). ***Work in progress may nonetheless continue until 31 December 2017. The IMI Joint Undertaking is a body as referred to in Article 185 of the Financial Regulation and Point 47 of the IIA of 17 May 2006.***

Justification

By analogy with the conclusions of the trilogue of 7 March 2007 on the Joint Undertaking for ITER, the IMI JU is also to be considered as a Community agency for the purpose of the application of point 47 of the IIA. This has to be reflected in the legal bases referred to in the Regulation.

Amendment 13
Article 3, point (b)

(b) support the implementation of the research priorities as set out by the Research Agenda of the Joint Technology Initiative on "Innovative Medicines" (hereinafter referred to as "Research Activities"), notably by awarding grants

(b) support the implementation of the research priorities as set out by the Research Agenda of the Joint Technology Initiative on "Innovative Medicines" (hereinafter referred to as "Research Activities"), notably by awarding grants

following competitive calls for proposals;

following competitive calls for proposals
*relating to research to be carried out
exclusively in the Member States and the
countries associated with the Seventh
Framework Programme;*

Justification

The IMI is primarily intended to support research in Europe.

Amendment 14
Article 6, paragraph 2

2. The running costs of the IMI Joint Undertaking shall be financed by its Members. The Community and EFPIA shall contribute in equal part to such running costs.

2. The running costs of the IMI Joint Undertaking shall be financed by its Members. The Community and EFPIA shall contribute in equal part to such running costs. ***The running costs shall not exceed 4% of the total budget.***

Justification

The annual report not only covers progress made but also any problems.

Amendment 15
Article 7, point (a)

(a) micro, small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC;

(a) micro, small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC, ***in accordance with the specific objectives set for them in the Seventh Framework Programme;***

Amendment 16
Article 7, point (g)

(g) ***qualified*** non-profit *patients* organisations.

(g) ***legally established*** non-profit *patients'* organisations.

Justification

The term 'qualified' is too vague and general; legal clarification is required.

Amendment 17
Article 8, paragraph 1

1. The IMI Joint Undertaking's Financial Regulation shall be based on the principles of the Framework Financial Regulation. It may depart from the Framework Financial Regulation where the specific operating needs of the IMI Joint Undertaking so require and subject to prior consultation with the Commission.

1. The financial rules applicable to the IMI Joint Undertaking may not depart from Regulation (EC, Euratom) No 2343/2002, unless its specific operating needs so require and subject to the prior consent of the Commission. The budgetary authority shall be informed of any such derogation.

Justification

Derogations from Regulation No 2343/2002 should be kept to an absolute minimum. The Joint Undertaking has to prove beyond any doubt that such a derogation is the only way to guarantee its proper functioning within the limits of its founding regulation.

Amendment 18
Article 8, paragraph 2 a (new)

2a. The IMI Joint Undertaking may appoint an external auditor in order to verify the fairness and accuracy of the annual accounts drawn up by the IMI Joint Undertaking.

Justification

The possibility of calling on an auditor is a good alternative way of ensuring satisfactory scrutiny of the annual accounts and the potential evaluation of contributions in kind by the members.

Amendment 19
Article 8, paragraph 2 b (new)

2b. The external auditor shall be responsible for ensuring satisfactory scrutiny of the annual accounts and the evaluation of the contributions made by the members and by the participants in the research projects.

Justification

The possibility of calling on an auditor is a good alternative way of ensuring satisfactory scrutiny of the annual accounts and the potential evaluation of contributions in kind by the members.

Amendment 20
Annex, Article 7 B (new)

Annual scientific and financial reports on the projects supported shall be submitted to the IMI Joint Undertaking by the participants. Such reports shall give details of the research activities carried out and the costs of such activities. Statements of expenditure shall be accompanied by an audit certificate. The external auditor shall examine the audit certificates and determine whether the in kind contributions match the contributions from public funds to the project..

Justification

The possibility of calling on an auditor is a good alternative way of ensuring satisfactory scrutiny of the annual accounts and the potential evaluation of contributions in kind by the members.

Amendment 21
Article 8, paragraph 2 d (new)

2d. The IMI Joint Undertaking may make use of ad hoc external audits.

Justification

The possibility of calling on an auditor is a good alternative way of ensuring satisfactory scrutiny of the annual accounts and the potential evaluation of contributions in kind by the members.

Amendment 22
Article 8, paragraph 2 e (new)

2e. The European Parliament shall be entitled to scrutinise the annual accounts of

the IMI Joint Undertaking.

Justification

The possibility of calling on an auditor is a good alternative way of ensuring satisfactory scrutiny of the annual accounts and the potential evaluation of contributions in kind by the members.

Amendment 23
Article 9, paragraph 1

1. The Staff Regulations of Officials of the European Communities, the Conditions of Employment of Other Servants of the European Communities and the rules adopted jointly by the European Community institutions for the purpose of applying these Staff Regulations and Conditions of Employment shall apply to the staff of the ARTEMIS Joint undertaking and its Executive Director..

1. The ARTEMIS Joint Undertaking shall recruit its staff in accordance with applicable regulations of the host country. The Commission may second to the ARTEMIS Joint Undertaking as many officials as may be needed.

Justification

Self-explanatory.

Amendment 24
Article 9, paragraph 2

2. In respect of its staff, the IMI Joint Undertaking shall exercise the powers conferred on the appointing authority by the Staff Regulations of Officials of the European Communities and on the authority empowered to conclude contracts by the Conditions of Employment of Other Servants of the European Communities.

deleted

Justification

Self-explanatory.

Amendment 25
Article 9, paragraph 3

3. The IMI Joint Undertaking shall, in agreement with the Commission, adopt the necessary implementing measures, **in accordance with arrangements provided for in article 110 of the Staff Regulations of Officials of the European Communities, and the Conditions of Employment of Other Servants of the European Communities.**

3. The IMI Joint Undertaking shall, in agreement with the Commission, adopt the necessary implementing measures **concerning the secondment** of officials of the European Communities.

Justification

Self-explanatory.

Amendment 26
Article 13, paragraph 1

1. The Commission shall present to the European Parliament and to the Council an annual report **on** the progress achieved by the IMI Joint Undertaking.

1. The Commission shall present to the European Parliament and to the Council an annual report **covering, in particular,** the progress achieved by the IMI Joint Undertaking.

Justification

The annual report should set out not just the progress achieved, but also any difficulties that may arise.

Amendment 27
Article 13, paragraph 2

2. **Two years after the establishment of the IMI Joint Undertaking, but in any case no later than 2010,** the Commission shall **conduct** an interim evaluation of the IMI Joint Undertaking with the assistance of independent experts. This evaluation shall cover the quality and efficiency of the IMI Joint Undertaking and progress towards the objectives set. **The Commission shall communicate the conclusions thereof, accompanied by its observations to the European Parliament and to the Council.**

2. **Before 31 December 2011,** the Commission shall **present to the European Parliament and to the Council** an interim evaluation of the IMI Joint Undertaking **prepared** with the assistance of independent experts. This evaluation shall cover the quality and efficiency of the IMI Joint Undertaking and progress towards the objectives set. The Commission shall communicate the conclusions thereof, accompanied by its observations to the European Parliament and to the Council.

Justification

Evaluation during the mandate is a precondition for assessing the progress made by the IMI Joint Undertaking and for taking the decisions stemming therefrom.

Amendment 28

Article 13, paragraph 3

3. **At the end of 2017**, the Commission shall conduct a final evaluation of the IMI Joint Undertaking with the assistance of independent experts. The results of the final evaluation shall be presented the European Parliament and to the Council.

3. **On 31 December 2013 or, if work in progress continues beyond that date, by 31 December 2017**, the Commission shall conduct a final evaluation of the IMI Joint Undertaking with the assistance of independent experts. The results of the final evaluation shall be presented the European Parliament and to the Council.

Justification

The conduct of a final evaluation in 2013 or 2017 is necessary to establish findings and measure the project's effects.

Amendment 29

Article 13, paragraph 4

4. Discharge for the implementation of the budget of the IMI Joint Undertaking shall be given by the European Parliament, **upon recommendation of the Council, in accordance with a procedure provided for by the Financial Regulation of the IMI Joint Undertaking.**

4. Discharge for the implementation of the budget of the IMI Joint Undertaking shall be given by the European Parliament, **taking into account a recommendation from the Council.**

Justification

See Amendment 4.

Amendment 30

Article 16

The IMI Joint Undertaking shall adopt rules governing the use and dissemination of research results which ensure that, where appropriate, intellectual property generated in Research Activities under this

The IMI Joint Undertaking shall adopt rules governing the use and dissemination of research results which ensure that, where appropriate, intellectual property generated in Research Activities under this

Regulation is protected, and that research results are used and *disseminated*.

Regulation is protected, and that research results are used and *published by the IMI Joint Undertaking*.

Justification

The term 'disseminated' is not precise enough in this instance. We have no way of knowing who would be responsible for disseminating the research results, or to whom they would be circulated. It would be more appropriate for the IMI Joint Undertaking to publish the results.

Amendment 31
Article 18

A host agreement shall be concluded between the IMI Joint Undertaking and Belgium concerning office accommodation, privileges and immunities and other support to be provided by Belgium to the IMI Joint Undertaking.

A host agreement shall be concluded between the IMI Joint Undertaking and Belgium concerning *the assistance with regard to* office accommodation, privileges and immunities and other support to be provided by Belgium to the IMI Joint Undertaking.

Justification

See Amendment 6.

Amendment 32
Article 19, paragraph 1

This Regulation shall enter into force on the *third* day of its publication in the Official Journal of the European Union.

This Regulation shall enter into force on the day of its publication in the Official Journal of the European Union.

Justification

Self-explanatory.

Amendment 33
Annex, Article 1, paragraph 3

3. The IMI Joint Undertaking shall be established as from the publication of these Statutes in the Official Journal of the European Union for *an initial* period ending on *31 December 2017*.

3. The IMI Joint Undertaking shall be established as from the publication of these Statutes in the Official Journal of the European Union for *a* period ending on *31 December 2013*.

Justification

See amendment to Recital 14.

Amendment 34
Annex, Article 1, paragraph 4

4. The initial period may be extended by amending these Statutes in accordance with the provisions of Article 21, taking into account the progress made towards achieving the objectives of the IMI Joint Undertaking and provided that financial sustainability is ensured.. **deleted**

Justification

The principle of public-private partnership must be time-limited so as to be fully effective and to measure the progress made.

Amendment 35
Annex, Article 2, paragraph 2, point (k)

(k) to publish information on the projects, including the name of the participants, and the amount of the financial contribution of the IMI Joint Undertaking. (k) to publish, ***inter alia on its website***, information on the projects, including the name of the participants, and the amount of the financial contribution of the IMI Joint Undertaking.

Justification

To ensure transparency and ease of access to information.

Amendment 36
Annex, Article 2, paragraph 2, point (i)

(i) to organise an annual meeting, hereafter referred to as a Stakeholder Forum, with interest groups to ensure openness and transparency of the Research Activities of the IMI Joint Undertaking with its stakeholders. (i) to organise an annual meeting, hereafter referred to as a Stakeholder Forum, ***an open meeting for relevant organisations with an interest in biomedical research to provide feedback on IMI activities***, with interest groups to ensure openness and transparency of the Research Activities of the IMI Joint Undertaking with its

stakeholders.

Justification

To ensure transparency and ease of access to information.

Amendment 37
Annex, Article 4

The bodies IMI Joint Undertaking shall be the Board, the Executive Office and the Scientific Committee.

The bodies *of the* IMI Joint Undertaking shall be the Board, the Executive **Director** and the Scientific Committee.

Justification

In line with other Community bodies set up in accordance with Article 185 of the Financial Regulation, it is the Executive Director (with the assistance of a secretariat under his responsibility) who shall be a body of the JU; it is inconsistent to create an Executive Office.

Amendment 38
Annex, Article 5, paragraph 1, point (b)

(b) the voting right of any new Member shall be determined in proportion to its contribution towards the total contributions to the activities of the IMI Joint Undertaking;

(b) the voting right of any new Member shall be determined in proportion to its contribution towards the total contributions to the activities of the IMI Joint Undertaking. **However, the total number of votes held by new Members may not exceed the total number of votes held by the Founding Members;**

Justification

The founding members are responsible in law for the operation of the IMI Joint Undertaking. To ensure effective governance, the Board must opt for an operationally effective configuration.

Amendment 39
Annex, Article 5, paragraph 1, point (c)

(c) the vote of each Member shall be indivisible;

(c) the vote of each Member shall be indivisible; **there shall be no proxy voting;**

Justification

There should be no provision for proxy voting. Only those present should be entitled to vote in order to avoid any possible confusion.

Amendment 40

Annex, Article 5, paragraph 2, point (c), indents 9 to 13

- | | |
|---|--|
| <ul style="list-style-type: none">– approve the guidelines on evaluation and selection of project proposals as proposed by the Executive Office;– approve the list of selected project proposals;– appoint the Executive Director, provide guidance and direction to the Executive Director, monitor the Executive Director's performance and, if necessary, replace the Executive Director;– approve the organisational structure of the Executive Office based on recommendations of the Executive Director;– approve the financial regulation of the IMI Joint Undertaking in accordance with Article 11; | <ul style="list-style-type: none">– approve the guidelines on evaluation and selection of project proposals as proposed by the Executive Director;– approve the list of selected project proposals;– appoint the Executive Director, provide guidance and direction to the Executive Director, monitor the Executive Director's performance and, if necessary, replace the Executive Director;– approve the financial rules of the IMI Joint Undertaking in accordance with Article 11, after consulting the Commission; |
|---|--|

Justification

In line with other Community bodies set up in accordance with Article 185 of the Financial Regulation, it is the Executive Director (with the assistance of a secretariat under his responsibility) who shall be a body of the JU; it is inconsistent to create an Executive Office.

Amendment 41

Annex, Article 5, paragraph 3, subparagraph c a (new)

(ca) Three Members of the European Parliament may attend meetings as observers and shall be invited by the Board.

Justification

The European Parliament should be represented on the Board of the IMI Joint Undertaking. Three Members allow for balance among the political groups. Having an uneven number of representatives has proved its worth in practice.

Amendment 42
Annex, Article 5, paragraph 3 a (new)

3a. The Board shall inform the Member States of decisions concerning the Research Agenda of the IMI Joint Technology Initiative.

Justification

The Member States must be fully informed about the decisions concerning the research agenda, to enable them to play their part, in accordance with subsidiarity, with regard to disseminating information about the research agenda and implementing that agenda at national level.

Amendment 43
Annex, Article 6, title and paragraph 1

Executive **Office**

Executive **Director**

1. The Executive Office shall be composed of an Executive Director and supporting staff.

Justification

See Amendment 38.

Amendment 44
Annex, Article 6, paragraph 2, introductory part, points (a) to (d) and point (e), introductory part

2. The tasks of the *executive office* are the following:

(a) The Executive Office shall be in charge of the day-to-day management of the IMI Joint Undertaking;

(b) The Executive **Office** shall be responsible for the operational aspects of the IMI Joint Undertaking;

2. The tasks of the *Executive Director* are the following:

(b) The Executive **Director, assisted by his secretariat**, shall be responsible for the operational aspects of the IMI Joint

- Undertaking;
- (c) The Executive **Office** shall be responsible for the communication activities related to the IMI Joint Undertaking;
- (d) The Executive **Office** shall manage appropriately the public and private funds;
- (e) The Executive **Office** shall in particular:

- (c) The Executive **Director, assisted by his secretariat**, shall be responsible for the communication activities related to the IMI Joint Undertaking;
- (d) The Executive **Director, assisted by his secretariat**, shall manage appropriately the public and private funds;
- (e) The Executive **Director, assisted by his secretariat**, shall in particular:

Justification

See Amendment 38.

Amendment 45

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 Stakeholder Forum**;

Justification

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

Amendment 46

Annex, Article 6, paragraph 7, point (g)

(g) **submit to the Board his/her proposal(s) concerning the organisation structure of the Executive Office and organise**, direct and supervise the staff of the IMI Joint Undertaking;

(g) direct and supervise the staff of the IMI Joint Undertaking;

Justification

See Amendment 38.

Amendment 47
Annex, Article 7, paragraph 1

The Scientific Committee is an advisory body to the Board and it shall conduct its activities in close liaison and with the support of the Executive **Office**.

1. The Scientific Committee is an advisory body to the Board and it shall conduct its activities in close liaison and with the support of the Executive **Director**.

Justification

See Amendment 38.

Amendment 48
Annex, Article 7, paragraph 6, point (c)

(c) advise the Board and the Executive **Office** on the scientific achievements described in the annual activity report;

(c) advise the Board and the Executive **Director** on the scientific achievements described in the annual activity report;

Justification

See Amendment 38.

Amendment 49
Annex, Article 8, paragraph 6 a (new)

6a. The evaluation of proposals shall establish whether the funds requested are commensurate with the work involved in carrying out the project.

Justification

The evaluation of each of the research proposals must ascertain whether the proposed budget is adequate for the work to be carried out, and the true value of monetary contributions must be evaluated by the Commission.

Amendment 50
Annex, Article 11, title and paragraph 1

Financial **Regulation**

1. The IMI Joint Undertaking's financial **regulation** shall be **agreed and** adopted by

Financial **Rules**

1. The IMI Joint Undertaking's financial **rules** shall be adopted by the Board **after**

the Board.

consulting the Commission.

Justification

See Amendment 17.

Amendment 51
Annex, Article 11, paragraph 2

2. The purpose of the financial **regulation** is to ensure the sound financial management of the IMI Joint Undertaking.

2. The purpose of the financial **rules** is to ensure the sound financial management of the IMI Joint Undertaking.

Justification

See Amendment 17.

Amendment 52
Annex, Article 11, paragraph 3

3. The IMI Joint Undertaking's *Financial Regulation shall be based on the principles of the Framework Financial Regulation. It may depart from the Framework Financial Regulation where the* specific operating needs *of the IMI Joint Undertaking* so require and subject to prior **consultation** *with* the Commission.

3. The IMI Joint Undertaking's *financial rules may not depart from Regulation (EC, Euratom) No 2343/2002, unless its* specific operating needs so require and subject to *the* prior **consent of** the Commission. *The budgetary authority shall be informed of any such derogation.*

Justification

See Amendment 17.

Amendment 53
Annex, Article 12, paragraph 5

5. The annual accounts and balance sheets for the preceding year shall be submitted to the Court of Auditors of the European Communities. An audit may be executed by the Court of Auditors in accordance with its standard procedures.

5. The annual accounts and balance sheets for the preceding year shall be submitted to the Court of Auditors of the European Communities **and to the budgetary authority**. An audit may be executed by the Court of Auditors in accordance with its standard procedures.

Justification

Accounts and balance sheets need to be sent to the two arms of the budgetary authority for information.

Amendment 54

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.

Amendment 55

Annex, Article 14, paragraph 1

1. The staff resources shall be determined in the establishment plan to be set out in the annual budget.

1. The staff resources shall be determined in the establishment plan to be set out in the annual budget ***and to be forwarded by the Commission to the European Parliament and the Council together with the preliminary draft general budget of the European Union.***

Justification

As is the case with the Joint Undertakings already in existence, the IMI JU's establishment plan should be published by the Commission together with the PDB.

Amendment 56

Annex, Article 14, paragraph 2

2. The members of the staff of the IMI Joint Undertaking shall be temporary agents and contract agents and shall have fixed term contracts extendable once up to a maximum total period of seven years.

deleted

Justification

Members of the IMI Joint Undertaking staff may be subject to different forms of contract. A flexible approach should allow a degree of freedom in the choice of contracts.

Amendment 57

Annex, Article 17, paragraph 5, point (a)

(a) micro, small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC;

(a) micro, small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC, ***in accordance with the specific objectives set for them by the Seventh Framework Programme;***

Amendment 58

Annex, Article 21, paragraph 1

1. Any Member of the IMI Joint Undertaking may make a proposal to the Board for the amendment of these Statutes.

Does not affect English version

Justification

Does not affect English version.

Amendment 59

Annex, Article 21, paragraph 2

2. Amendment to these Statutes shall be approved by the Board. If such amendment affects the overall *principals* and objectives of these Statutes, in particular any amendment to Article 1, first indent of Article 5(2)(c), Article 8(3) and Article 21 shall be subject to approval by the Council based on a proposal by the Commission.

2. Amendment to these Statutes shall be approved by the Board. If such amendment affects the overall *principles* and objectives of these Statutes, in particular any amendment to Article 1, *the* first indent of Article 5(2)(c), Article 8(3) and Article 21 shall be subject to approval by the Council based on a proposal by the Commission, ***and after consultation of the European Parliament.***

Justification

The European Parliament needs to be consulted on any important changes to the JU's statutes.

Amendment 60
Annex, Article 22, paragraph 3, point (a)

(a) Each participant in a project shall remain the owner of the intellectual property that it introduces into a project, and shall remain the owner of the intellectual property that it generates in a project unless otherwise mutually agreed by the participants in a project. The terms and conditions of access rights and licenses with regard to the intellectual property introduced into or generated by participants in a project, shall be defined in the Grant Agreement and the Project Agreement of the project concerned.

(a) Each participant in a project shall remain the owner of the intellectual property that it introduces into a project, and shall remain the owner of the intellectual property that it generates in a project unless otherwise mutually agreed by the participants in a project. The terms and conditions of access rights and licenses with regard to the intellectual property introduced into or generated by participants in a project, shall be defined in the Grant Agreement and the Project Agreement of the project concerned. ***Project participants should establish any cases of co-ownership of intellectual property arising from projects.***

Justification

As the IMI undertaking is a joint one, provision should be made for establishing co-ownership of intellectual property in cases where several participants achieve results determined by the various stakeholders.

Amendment 61
Annex, Article 23 a (new)

Article 23a

Host Agreement

A host agreement shall be concluded between the IMI Joint Undertaking and Belgium.

Justification

For the sake of consistency, the traditional host agreement clause should also be included in the statutes. See also Amendment 6.

EXPLANATORY STATEMENT

1) Background

Research and innovation contribute directly to the prosperity and wellbeing of individuals and society. The main aim of technological research and development policy is to turn the European Union into a leading knowledge economy.

The European Union must make it possible to achieve the greatest possible cooperation at various levels, coordinate European and national policies more effectively, strengthen structural capacity and links between research teams and, finally, enhance the mobility of researchers and ideas.

Joint technological initiatives (JTIs) are instruments defined in the specific programme 'Cooperation' of the Seventh Framework Programme. The JTI are the result of the work accomplished by the European technological platforms (ETP) launched under the Sixth Framework Programme to bring together public and private stakeholders to set up and implement joint research programmes in the field of industrial research.

In a small number of cases, ETPs have achieved such an ambitious scale and scope that they considerable amounts of public and private investment will have to be mobilised in order to implement their research programmes.

In contrast to the traditional approach, which involved providing projects with public funding on a case-by-case basis, JTIs are designed for large-scale research programme having joint strategic research objectives. This new approach is designed to generate critical mass in terms of European research and innovation by consolidating the activities of the European scientific community in the main strategic areas. It will harmonise the funding of projects to ensure that research results can be put to use more swiftly. As one of these JTIs, the innovative medicines initiative (IMI) will finance pan-European public/private partnerships in the field of biomedical research.

2) Challenges

Although the EU is a world leader in many technologies, it needs to address an increasing number of challenges not only from its traditional competitors, but also from the emerging economies. The joint programmes can obtain results which the Member States could not achieve by acting alone.

The emerging strength of the Indian and Chinese economies in the area of high-value-added technology is inducing the European Union to enhance its potential with regard to innovation, research and technology. Innovation is one of the keys to the future success of the revised Lisbon Strategy for growth and employment.

The EU seems, however, to be a victim of the paradoxical failings which prevent it from exploiting its potential to the full: an inability to convert the fruits of innovation into new

products, patents and jobs; a large number of innovative small and medium-sized enterprises (SMEs) which are finding it difficult to grow and succeed at world level.

More particularly, the productivity of pharmaceutical research and development has been declining for three decades, although financial investment has been steadily increasing. In 25 years, the amount of expenditure on research and development per pharmaceutical product placed on the market rose from € 54 million to € 880 million, equivalent to an annual increase of 11.8%. At the same time, there has been a significant drop in the duration of new drugs' effective profitability. The average duration of the clinical development process has risen from 2.5 years in the 1960s to 6.5 years in the 1990s. As an additional problem, there has been a rise in the failure rate of various stages of the testing process for new molecules. An increasing number of compounds is having to be tested to find one which would be placed on the market.

The Seventh Framework Programme for research, which covers the period from 2007-2013, offers the EU an opportunity to bring its research policy into line with its economic and social ambitions by consolidating the European Research Area (ERA). To achieve that objective, the Commission wishes to increase the EU's annual research budget and thereby stimulate greater national and private investment. The implementation of the Seventh Framework Programme must also meet the research and knowledge requirements of industry and of European policy objectives in general.

The Commission, the Member States and industry have decided to join forces by investing together in strategic research programmes. The Commission has proposed four joint technological initiatives. These JTIs will enable industry, the Member States and the Commission to pool their resources in the context of targeted research programmes.

3) A new joint approach

The IMI is a unique initiative jointly implemented by the Commission and the EFPIA (European Federation for Pharmaceutical Industries and Associations). It will bring together public authorities, patients, universities, hospitals and representatives of the pharmaceutical industry to enable important progress to be made and address the complex issues involved in pre-competitive research and development.

The IMI JU will have a total budget of EUR 2 billion for the period 2008-2013. The Commission has allocated EUR 1 billion to the IMI JU under the Seventh Framework Programme. The Community's contribution will be paid in full to SMEs and universities to fund research which could be used by the pharmaceutical industry. The big pharmaceutical companies will make an equivalent contribution and ensure the involvement of these SMEs and universities. The IMI JU will, consequently, help boost private investment in R&D, improve knowledge transfer between universities and firms, and increase the participation of small businesses in the European research sector.

4) Appreciable benefits

The innovative medicines initiative will aim to support the development of new knowledge, new tools and new methods in order to ensure more appropriate and safer medicines reach the

market more rapidly. It will lead to better care for patients, particularly those suffering from cancer or cerebral, inflammatory, metabolic or infectious diseases.

The purpose of the IMI JU is not to produce specific treatments but to identify bottlenecks in the R&D process, including pharmacovigilance, drug efficacy, knowledge management, education and training. Progress in these four areas will make it possible to improve research with a view to discovering, and speeding up the development of, better medicines, particularly for the treatment of 'neglected diseases'.

The collective approach developed by the IMI will reduce the risks involved for small firms and help them to develop products more swiftly by providing them with access to a common infrastructure, resources and equipment.

5) How the system will work

The IMI will involve a non-profit joint undertaking pursuant to *Article 171 of the Treaty*. This joint undertaking will be supported by an executive office jointly funded and managed by the Commission and the EFPIA. The latter will publish calls for research proposals. Groups of partners (universities, SMEs, bio-pharmaceutical companies, public authorities, patients) will form a public-private partnership to propose research initiatives. A public-private partnership shall include at least one university and/or SME, and one EFPIA member company.

The Commission and the EFPIA have together drawn up a strategic research agenda for the IMI. This document contains recommendations concerning the main bottlenecks.

6. Conclusion

Europe needs a new approach to research in areas which offer promising prospects for our competitiveness and well-being. The proposals show that the Commission must now adopt a fresh approach to addressing Europe's requirements in that field. These public-private partnerships offer a new and promising alternative for pharmaceutical research, but also for all other areas of research activities.

The rapporteur is pleased that approaches of this kind are being implemented. Some changes are proposed to the general framework laid down by the Commission proposal in order to clarify certain points. The distribution of intellectual property rights should be decided within the IMI JU, which will determine how any potential co-ownership issues should be resolved.

The interests of SMEs must not be sacrificed to those of other, bigger sections of the industry. It is an essential pre-requisite, therefore, for the needs of SMEs to be taken more fully into account and for support measures to be taken to reduce any additional administrative burdens which might be imposed on them.

13.11.2007

OPINION OF THE COMMITTEE ON BUDGETS

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: Jutta Haug

SHORT JUSTIFICATION

Commission proposal

Joint Technology Initiatives (JTIs) are introduced in the Seventh Framework Programme¹ (FP7) as a new way of realising public-private partnerships in research at European level. JTIs arise primarily from the work of European Technology Platforms (ETPs). In a small number of cases, ETPs have reached such an ambitious scale and scope that they will require the mobilisation of considerable public and private investments as well as substantial research resources to implement important elements of their Strategic Research Agendas. JTIs are proposed as means of meeting the needs of this small number of ETPs.

In the Cooperation Specific Programme² six areas are identified where a JTI could have particular relevance: hydrogen and fuel cells, aeronautics and air transport, innovative medicines, embedded computing systems, nanoelectronics and GMES (global monitoring for environment and security).

Against this background, the Innovative Medicines Initiative Joint Undertaking (IMI JU) is the legal entity that will be responsible for implementation of the Joint Technology Initiative on Innovative Medicines (IMI JTI). The present proposal relates to the setting-up of the IMI JU under Article 171 of the Treaty.

The IMI JU should be considered as a Community body and be established for a period ending on 31 December 2017. It will have its seat in Brussels, Belgium.

¹ OJ L 412, 30.12.2006, p. 1

² OJ L 400, 30.12.2006, p. 66-241.

It will be founded by the European Community, represented by the EC, and the European Federation of Pharmaceutical Industries and Associations, EFPIA. The activities of the IMI JU will be jointly funded by its founders. The European Community and EFPIA will contribute in equal parts to the running costs of the IMI JU. The research activities will be jointly funded through contributions by the EFPIA member companies with resources (personnel, equipment, consumables, etc.), and a matching contribution from the European Community.

Financial implications

The IMI JU will have a total budget of EUR 2 billion. The EC will contribute with EUR 1 billion from FP7. The remaining EUR 1 billion will be contributed by EFPIA and the research-based pharmaceutical companies that are full members of EFPIA.

Two new budget lines will be created for the EU contribution:

08.02 01 10 "Operational expenditures for research activities of the IMI Joint Undertaking"
08.02 01 20 "Support expenditures for running costs of the IMI Joint Undertaking"

with the following expenditure profile:

Expenditure type	Section no.		Year 2008	2009	2010	2011	2012	2013 and later	Total
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Operational expenditure¹

Commitment Appropriations (CA)	8.1.	a	122 700	76 800	95 800	155 400	294 300	215 000	960 000
Payment Appropriations (PA)		b	122 700	76 800	95 800	155 400	294 300	215 000	960 000

Administrative expenditure²

Technical & administrative assistance (NDA)	8.2.4.	c	2 300	3 200	4 200	4 600	5 700	20 000	40 000
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TOTAL REFERENCE AMOUNT

Commitment Appropriations		a+c	125 000	80 000	100 000	160 000	300 000	235 000	1 000 000
Payment Appropriations		b+c	125.000	80.000	100 000	160 000	300 000	235 000	1 000 000

Assessment

The draftswoman's amendments are mainly based on two concerns:

1) The JU is established for an initial period ending on 31 December 2017 (which may even be extended to a later date), whereas the MFF only covers the period up to 2013. Therefore, any request for Community funding for the IMI JU after 2013 has to be newly evaluated in

¹ Expenditure 08.02 01 10 "Operational expenditures for research activities of the IMI Joint Undertaking"

² Expenditure 08.02 01 20 "Support expenditures for running costs of the IMI Joint Undertaking"

the context of the negotiations for a new financial framework.

As for the current period, the proposal - although falling under Heading 1a with its dwindling margins - is compatible with the MFF, for the simple reason, that the EU contribution required is taken from the FP7 and has as such already been included in the Commission's financial programming.

Nevertheless, your draftswoman would like to point out that no financial commitments can be made for the time after the current MFF (Amendment 1).

2) By analogy with the negotiations on the ITER Joint Undertaking at the beginning of 2007 which led to the Conclusions agreed at the Trilogue of 7 March 2007, the IMI JU has to be considered as an agency within the meaning of Article 185 of the Financial Regulation and is therefore subject to an agreement by the budgetary authority on its financing (Amendments 2, 3, 7 and 11).

At the same time, if the basic assumption is that the IMI JU is to be treated as an agency for budgetary purposes, it has to be consistent with the general approach on agencies that the Committee on Budgets has developed over the past years. Your draftswoman therefore presents a series of amendments which guarantee such a consistent approach (Amendments 4-6, 8-10 and 12-26).

AMENDMENTS

The Committee on Budgets calls on the Committee on Industry, Research and Energy, as the committee responsible, to incorporate the following amendments in its report:

Draft legislative resolution

Amendment 1 Paragraph 1 a (new)

1a. Considers that the reference amount indicated in the legislative proposal must be compatible with the ceiling of heading 1a of the current multiannual financial framework 2007 - 2013 and with the provisions of Point 47 of the Interinstitutional Agreement (IIA) of 17 May 2006; notes that any financing beyond 2013 shall be evaluated in the context of the negotiations for the next financial framework;

Amendment 2 Paragraph 1 b (new)

1b. Recalls that the opinion delivered by the Committee on Budgets does not pre-empt the outcome of the procedure laid down in Point 47 of the IIA of 17 May 2006 which applies to the setting up of the Innovative Medicines Initiative Joint Undertaking;

Proposal for a regulation

Text proposed by the Commission

Amendments by Parliament

Amendment 3 Citations 1 a and 1 b (new)

Having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities¹ (Financial Regulation), and in particular Article 185 thereof,

Having regard to the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management² (IIA), and in particular Point 47 thereof,

¹ OJ L 248, 16.9.2002, p. 1. Regulation as amended by Regulation (EC, Euratom) No 1995/2006 (OJ L 390, 30.12.2006, p. 1).

² OJ C 139, 14.6.2006, p. 1.

Justification

By analogy with the conclusions of the trilogue of 7 March 2007 on the Joint Undertaking for ITER, the IMI JU is also to be considered as a Community agency for the purpose of the application of point 47 of the IIA. This has to be reflected in the legal bases referred to in the Regulation.

Amendment 4 Recital 16

(16) The IMI Joint Undertaking should be a body set up by the Communities and discharge for the implementation of its budget should be given by the European Parliament, ***on the recommendation of the Council, taking however into account the specificities resulting from the nature of JTIs as public-private partnerships and in particular from the private sector***

(16) The IMI Joint Undertaking should be a body set up by the Communities and discharge for the implementation of its budget should be given by the European Parliament, ***taking into account a recommendation from the Council.***

contribution to the budget.

Justification

By analogy with the conclusions of the trilogue of 7 March 2007 on the Joint Undertaking for ITER, the European Parliament should be given full and unconditional responsibility for the discharge of the implementation of the budget of the IMI JU.

Amendment 5

Recital 27

(27) The IMI Joint Undertaking should have, subject to prior consultation with the Commission, a distinct Financial Regulation based on the principles of the framework financial regulation which takes into account its specific operating needs arising, in particular, from the need to combine Community and private funding to support research and development activities in an efficient and timely manner.

(27) The financial rules applicable to the IMI Joint Undertaking should not depart from Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of the Financial Regulation¹, unless specifically required for its operating needs, in particular the need to combine Community and private funding to support research and development activities in an efficient and timely manner. The prior consent of the Commission should be required for the adoption of any rules which derogate from Regulation (EC, Euratom) No 2343/2002. The budgetary authority should be informed of such derogations.

¹ OJ L 357, 31.12.2002, p. 72.

Justification

Derogations from Regulation No 2343/2002 should be kept to an absolute minimum. The Joint Undertaking has to prove beyond any doubt that such a derogation is the only way to guarantee its proper functioning within the limits of its founding regulation.

Amendment 6

Recital 33

(33) The IMI Joint Undertaking should be established in Brussels, Belgium. A host agreement should be concluded between the

(33) The IMI Joint Undertaking should be established in Brussels, Belgium. A host agreement should be concluded between the

IMI Joint Undertaking and Belgium concerning office accommodation, privileges and immunities and other support to be provided by Belgium to the IMI Joint Undertaking.

IMI Joint Undertaking and Belgium concerning ***the host country's assistance with regard to*** office accommodation, privileges and immunities and other support to be provided by Belgium to the IMI Joint Undertaking.

Justification

It should be clearly stipulated that the host country of any agency or similar Community body is expected to provide financial and all other assistance necessary to facilitate the setting-up and running of the Community body.

Amendment 7
Article 1, paragraph 1

1. For the implementation of the Joint Technology Initiative on Innovative Medicines, a Joint Undertaking is hereby set up for a period ending on 31 December 2017 (hereinafter referred to as "IMI Joint Undertaking"). This period may be extended by ***the Council***.

1. For the implementation of the Joint Technology Initiative on Innovative Medicines, a Joint Undertaking is hereby set up for a period ending on 31 December 2017 (hereinafter referred to as "IMI Joint Undertaking"). This period may be extended by ***a revision of this Regulation. The IMI Joint Undertaking is a body set up in accordance with Article 185 of the Financial Regulation and Point 47 of the IIA of 17 May 2006.***

Justification

For any extension of the Joint Undertaking's lifetime, the respective legislative procedure has to be followed. See Amendment 3.

Amendment 8
Article 8, paragraph 1

1. ***The IMI Joint Undertaking's Financial Regulation shall be based on the principles of the Framework Financial Regulation. It may depart from the Framework Financial Regulation where the specific operating needs of the IMI Joint Undertaking so require and*** subject to prior ***consultation with*** the Commission.

1. ***The financial rules applicable to the IMI Joint Undertaking may not depart from Regulation (EC, Euratom) No 2343/2002, unless specifically required for its operating needs*** and subject to prior ***consent*** of the Commission. ***The budgetary authority shall be informed of such derogations.***

Justification

See Amendment 5.

Amendment 9
Article 13, paragraph 4

4. Discharge for the implementation of the budget of the IMI Joint Undertaking shall be given by the European Parliament, **upon recommendation of the Council, in accordance with a procedure provided for by the Financial Regulation of the IMI Joint Undertaking.**

4. Discharge for the implementation of the budget of the IMI Joint Undertaking shall be given by the European Parliament, **taking into account a recommendation from the Council.**

Justification

See Amendment 4.

Amendment 10
Article 18

A host agreement shall be concluded between the IMI Joint Undertaking and Belgium concerning office accommodation, privileges and immunities and other support to be provided by Belgium to the IMI Joint Undertaking.

A host agreement shall be concluded between the IMI Joint Undertaking and Belgium concerning **the host country's assistance with regard to** office accommodation, privileges and immunities and other support to be provided by Belgium to the IMI Joint Undertaking.

Justification

See Amendment 6.

Amendment 11
Annex, Article 1, paragraph 3

3. The IMI Joint Undertaking shall be established as from the publication of these Statutes in the Official Journal of the European Union for an initial period ending on 31 December 2017.

3. The IMI Joint Undertaking shall be established as from the publication of these Statutes in the Official Journal of the European Union for an initial period ending on 31 December 2017. **It is a body set up in accordance with Article 185 of the Financial Regulation and Point 47 of the**

IIA of 17 May 2006.

Justification

See Amendment 7.

Amendment 12
Annex, Article 4

The bodies IMI Joint Undertaking shall be the Board, the Executive Office and the Scientific Committee.

The bodies *of the* IMI Joint Undertaking shall be the Board, the Executive **Director** and the Scientific Committee.

Justification

In line with other Community bodies set up in accordance with Article 185 of the Financial Regulation, it is the Executive Director (with the assistance of a secretariat under his responsibility) who shall be a body of the JU; it is inconsistent to create an Executive Office.

Amendment 13
Annex, Article 5, paragraph 2, point (c), indents 9 to 13

– approve the guidelines on evaluation and selection of project proposals as proposed by the Executive **Office**;

- approve the list of selected project proposals;

- appoint the Executive Director, provide guidance and direction to the Executive Director, monitor the Executive Director's performance and, if necessary, replace the Executive Director;

– **approve the organisational structure of the Executive Office based on recommendations of the Executive Director**;

– approve the financial **regulation** of the IMI Joint Undertaking in accordance with Article 11;

– approve the guidelines on evaluation and selection of project proposals as proposed by the Executive **Director**;

- approve the list of selected project proposals;

- appoint the Executive Director, provide guidance and direction to the Executive Director, monitor the Executive Director's performance and, if necessary, replace the Executive Director;

– approve the financial **rules** of the IMI Joint Undertaking in accordance with Article 11, **after consulting the Commission**;

Justification

See Amendments 5, 8 and 12.

Amendment 14
Annex, Article 6, title and paragraph 1

Executive **Office**

Executive **Director**

1. The Executive Office shall be composed of an Executive Director and supporting staff.

Justification

See Amendments 12 and 13.

Amendment 15
Annex, Article 6, paragraph 2, introductory part, points (a) to (d) and point (e), introductory part

2. The tasks of the *executive office* are the following:

2. The tasks of the *Executive Director* are the following:

(a) The Executive Office shall be in charge of the day-to-day management of the IMI Joint Undertaking;

(b) The Executive **Director, assisted by his secretariat**, shall be responsible for the operational aspects of the IMI Joint Undertaking;

(b) The Executive **Office** shall be responsible for the operational aspects of the IMI Joint Undertaking;

(c) The Executive **Office** shall be responsible for the communication activities related to the IMI Joint Undertaking;

(c) The Executive **Director, assisted by his secretariat**, shall be responsible for the communication activities related to the IMI Joint Undertaking;

(d) The Executive **Office** shall manage appropriately the public and private funds;

(d) The Executive **Director, assisted by his secretariat**, shall manage appropriately the public and private funds;

(e) The Executive **Office** shall in particular:

(e) The Executive **Director, assisted by his secretariat**, shall in particular:

Justification

See Amendments 12, 13 and 14.

Amendment 16
Annex, Article 6, paragraph 7, point (g)

(g) **submit to the Board his/her proposal(s) concerning the organisation structure of the Executive Office and organise**, direct and supervise the staff of the IMI Joint Undertaking;

(g) direct and supervise the staff of the IMI Joint Undertaking;

Justification

See Amendments 12, 13, 14 and 15.

Amendment 17
Annex, Article 7, paragraph 1

The Scientific Committee is an advisory body to the Board and it shall conduct its activities in close liaison and with the support of the Executive **Office**.

1. The Scientific Committee is an advisory body to the Board and it shall conduct its activities in close liaison and with the support of the Executive **Director**.

Justification

See Amendments 12, 13, 14, 15 and 16.

Amendment 18
Annex, Article 7, paragraph 6, point (c)

(c) advise the Board and the Executive **Office** on the scientific achievements described in the annual activity report;.

(c) advise the Board and the Executive **Director** on the scientific achievements described in the annual activity report;

Justification

See Amendments 12, 13, 14, 15, 16 and 17.

Amendment 19
Annex, Article 11, title and paragraph 1

Financial **Regulation**

1. The IMI Joint Undertaking's financial **regulation** shall be **agreed and** adopted by the Board.

Financial **Rules**

1. The IMI Joint Undertaking's financial **rules** shall be adopted by the Board **after having consulted the Commission.**

Justification

See Amendments 5, 8, 12 and 13.

Amendment 20
Annex, Article 11, paragraph 2

2. The purpose of the financial **regulation** is to ensure the sound financial management of the IMI Joint Undertaking.

2. The purpose of the financial **rules** is to ensure the sound financial management of the IMI Joint Undertaking.

Justification

See Amendments 5, 8, 12, 13 and 20.

Amendment 21
Annex, Article 11, paragraph 3

3. The IMI Joint Undertaking's **Financial Regulation shall be based on the principles of the Framework Financial Regulation. It may depart from the Framework Financial Regulation where the** specific operating needs **of the IMI Joint Undertaking so require and subject to prior consultation with the Commission.**

3. The IMI Joint Undertaking's **financial rules may not depart from Regulation (EC, Euratom) No 2343/2002, unless necessary for its** specific operating needs. **The prior consent of the Commission shall be required for the adoption of any rules which derogate from Regulation (EC, Euratom) No 2343/2002. The budgetary authority shall be informed of such derogations.**

Justification

See Amendments 5, 8, 12, 13, 20 and 21.

Amendment 22
Annex, Article 12, paragraph 5

5. The annual accounts and balance sheets for the preceding year shall be submitted to the Court of Auditors of the European Communities. An audit may be executed by the Court of Auditors in accordance with its standard procedures.

5. The annual accounts and balance sheets for the preceding year shall be submitted to the Court of Auditors of the European Communities ***and to the budgetary authority***. An audit may be executed by the Court of Auditors in accordance with its standard procedures.

Justification

Accounts and balance sheets need to be sent to the two arms of the budgetary authority for information.

Amendment 23
Annex, Article 14, paragraph 1

1. The staff resources shall be determined in the establishment plan to be set out in the annual budget.

1. The staff resources shall be determined in the establishment plan to be set out in the annual budget ***and to be forwarded by the Commission to the European Parliament and the Council together with the preliminary draft budget of the European Union.***

Justification

As is the case with the Joint Undertakings already in existence, the IMI JU's establishment plan should be published by the Commission together with the PDB.

Amendment 24
Annex, Article 21, paragraph 2

2. Amendment to these Statutes shall be approved by the Board. If such amendment affects the overall *principals* and objectives

2. Amendment to these Statutes shall be approved by the Board. If such amendment affects the overall *principles* and objectives

of these Statutes, in particular any amendment to Article 1, first indent of Article 5(2)(c), Article 8(3) and Article 21 shall be subject to approval by the Council based on a proposal by the Commission.

of these Statutes, in particular any amendment to Article 1, *the* first indent of Article 5(2)(c), Article 8(3) and Article 21 shall be subject to approval by the Council based on a proposal by the Commission, ***and after consultation of the European Parliament.***

Justification

The European Parliament needs to be consulted on any important changes to the JU's statutes.

Amendment 25
Annex, Article 23 a (new)

Article 23a

Host Agreement

A host agreement shall be concluded between the IMI Joint Undertaking and the host state.

Justification

For the sake of consistency, the traditional host agreement clause should also be included in the statutes. See also Amendment 6.

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	BUDG 19.6.2007	
Drafts(wo)man Date appointed	Jutta Haug 20.9.2004	
Discussed in committee	8.10.2007	12.11.2007
Date adopted	12.11.2007	
Result of final vote	+: 15	-: 0
	0: 0	
Members present for the final vote	Reimer Böge, Gérard Deprez, Valdis Dombrovskis, Brigitte Douay, James Elles, Salvador Garriga Polledo, Catherine Guy-Quint, Jutta Haug, Alain Lamassoure, Janusz Lewandowski, Vladimír Maňka, Margaritis Schinas, László Surján, Gary Titley, Kyösti Virrankoski	

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 losing 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 to 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 Commission¹

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 Țîrle

PROCEDURE

Title	Establishment of the Innovative Medicines Initiative Joint Undertaking			
References	COM(2007)0241 - C6-0171/2007 - 2007/0089(CNS)			
Date of consulting Parliament	11.6.2007			
Committee responsible Date announced in plenary	ITRE 19.6.2007			
Committee(s) asked for opinion(s) Date announced in plenary	BUDG 19.6.2007	CONT 19.6.2007	ENVI 19.6.2007	JURI 19.6.2007
Not delivering opinions Date of decision	CONT 17.7.2007	JURI 3.10.2007		
Rapporteur(s) Date appointed	Françoise Grossetête 25.6.2007			
Discussed in committee	5.11.2007			
Date adopted	12.11.2007			
Result of final vote	+: -: 0:	35 0 0		
Members present for the final vote	Jan Březina, Renato Brunetta, Giles Chichester, Gianni De Michelis, Den Dover, Adam Gierek, Norbert Glante, András Gyürk, Fiona Hall, David Hammerstein, Ján Hudacký, Romana Jordan Cizelj, Werner Langen, Angelika Niebler, Reino Paasilinna, Atanas Papanizov, Miloslav Ransdorf, Herbert Reul, Teresa Riera Madurell, Andres Tarand, Britta Thomsen, Patrizia Toia, Nikolaos Vakalis, Dominique Vlasto			
Substitute(s) present for the final vote	Pilar Ayuso, Ivo Belet, Danutė Budreikaitė, Robert Goebbels, Françoise Grossetête, Satu Hassi, Edit Herczog, Vittorio Prodi, Esko Seppänen, Lambert van Nistelrooij			
Substitute(s) under Rule 178(2) present for the final vote	Eva Lichtenberger			