



**COUNCIL OF
THE EUROPEAN UNION**

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COMPET 413**

OUTCOME OF PROCEEDINGS

From : General Secretariat

No. prev. doc. 14789/07 RECH 346 COMPET 369

Subject : Proposal for a Council Regulation setting up the Innovative Medicines Initiative
Joint Undertaking

– General Approach

Delegations will find attached the text of General Approach on the above proposal as achieved by the Competitiveness Council on 23 November 2007.

Draft
COUNCIL REGULATION
setting up the Innovative Medicines Initiative Joint Undertaking

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 171 and 172 thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the European Parliament²,

Having regard to the opinion of the European Economic and Social Committee³,

¹ OJ C, , p. .
² Opinion of the European Parliament of (...).
³ Opinion delivered on (...).

Whereas:

- (1) Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013)⁴ hereinafter referred to as the "Seventh Framework Programme", provides for a Community contribution for the establishment up of long term public private partnerships in the form of Joint Technology Initiatives which could be implemented through Joint Undertakings within the meaning of Article 171 of the Treaty. These Joint Technology Initiatives result from the work of European Technology Platforms, already set up under the Sixth Framework Programme, and cover selected aspects of research in their field. They should combine private sector investment and European public funding, including funding from the Seventh Framework Programme;
- (2) Council Decision 971/2006/EC of 19 December 2006 concerning the specific programme "Cooperation" implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013)⁵ (hereinafter referred as the "Specific Programme Cooperation"), underlines the need for ambitious pan-European public private partnerships to accelerate the development of major technologies, large research actions at Community level including, in particular, Joint Technology Initiatives;
- (3) The Lisbon Growth and Jobs Agenda underscores the need to develop favourable conditions for investment in knowledge and innovation in Europe to boost competitiveness, growth and jobs in the Community,

⁴ OJ L 412, 30.12.2006, p.1.

⁵ OJ L 400, 30.12.2006, p. 86. Corrected version in OJ L 54, 22.2.2007 p. 30.

- (4) In its conclusions of 20 and 21 March 2003, of 22 September 2003 and of 24 September 2004, the Competitiveness Council highlighted the importance of further developing actions following the 3% Action Plans⁶, including the development of new initiatives aimed at intensifying co-operation between industry and the public sector in funding research to enhance trans-national public-private links,
- (5) In its conclusions of 4 December 2006 and of 19 February 2007, the Competitiveness Council and its conclusions of 9 March 2007 the European Council invited the Commission to present proposals for the setting up of Joint Technology Initiatives for such initiatives that have reached an appropriate stage of preparedness,
- (6) The “European Federation of Pharmaceutical Industries and Associations” (hereinafter referred to as "EFPIA") took the lead in establishing the European Technology Platform on "Innovative Medicines" under the Sixth Framework Programme. They developed a Strategic Research Agenda, based on an extensive consultation with public and private stakeholders. The Strategic Research Agenda described the research bottlenecks in the drug development process and recommends the scientific direction for a Joint Technology Initiative on "Innovative Medicines”,

⁶ COM(2003) 226 final.

- (7) The Joint Technology Initiative on "Innovative Medicines" responds to the Commission Communication of 1 July 2003 "A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action"⁷ and in particular to the recommendation regarding access to innovative medicines to secure the development of a competitive innovative-based industry. This Communication was a response to the Report "Stimulating Innovation and Improving the EU Science Base" adopted on 7 May 2002 of the High Level Group on innovation and provision of medicines - G10 Medicines. This Joint Technology Initiative also responds to the Commission Communication of 23 January 2002 on "Life Sciences and Biotechnology – a strategy for Europe (2002)"⁸,
- (8) The Joint Technology Initiative on "Innovative Medicines" also replies to the need for action as identified in the Report "Creating an Innovative Europe" of January 2006. This report identifies Pharmaceuticals as a key strategic area and it stresses the need for the Joint Technology Initiative on "Innovative Medicines" at European level.
- (9) The Joint Technology Initiative on "Innovative Medicines" should be a public-private partnership aiming at increasing investments in the biopharmaceutical sector in Europe in the Members States and countries associated to the Seventh Framework Programme. It should provide socio-economic benefits for European citizens, contribute to the health of European citizens, increase the competitiveness of Europe and help to establish Europe as the most attractive place for biopharmaceutical research and development.

⁷ COM (2003)383.

⁸ COM(2002)27.

- (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" which identified efficacy, safety, knowledge management and training as important areas.
- (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.
- (12) The Joint Technology Initiative on "Innovative Medicines" should deliver new approaches, methods and technologies, improve knowledge management of research results and data, and support the training of professionals. To this end it is necessary to set up a Joint Undertaking as a legal entity for the implementation of the Joint Technology Initiative on "Innovative Medicines". This Joint Undertaking is hereinafter referred to as the "IMI Joint Undertaking".
- (13) The objective of the IMI Joint Undertaking should be achieved through support of research activities by pooling resources from the public and private sectors. To that end, the IMI Joint Undertaking should be capable of organising competitive calls for proposals for supporting the research activities. Such research activities should respect fundamental ethical principles applicable in the Seventh Framework Programme.

- (14) The IMI Joint Undertaking should be set up for a period up to 31 December 2017 to ensure the appropriate management of research activities initiated but not concluded during the Seventh Framework Programme(2007-2013).
- (15) 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 Parliament⁹, 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) Founding members of the IMI Joint Undertaking should be the European Community and EFPIA.
- (17) EFPIA is a non-profit organization representing the research based pharmaceutical industry in Europe. The aim of EFPIA is to ensure and promote the technological and economic development of the pharmaceutical industry in Europe. EFPIA is open for membership to national associations of research based pharmaceutical companies, as well as directly to research based pharmaceutical companies. It applies general principles of openness and transparency for membership ensuring a wide industrial involvement.
- (18) EFPIA was created in 1978 from a merger between two European organisations - GIIP (initially created under French law in 1966) representing 9 European countries and PIA (created under Swiss law in 1967) representing EFTA national associations. EFPIA was set up under Swiss law with its permanent office in Brussels, Belgium.

⁹ Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the budget of the European Communities, OJ L 357, 31.12.2002 p. 72; corrigendum in OJ L 2, 7.12.2003, p. 39.

- (19) The IMI Joint Undertaking should be open to new members.
- (20) The rules for organisation and operation of the IMI Joint Undertaking should be laid down in the Statutes of the IMI Joint Undertaking as part of this Regulation.
- (21) A letter of commitment concerning the Statutes of the IMI Joint Undertaking has been signed by EFPIA and its research based pharmaceutical companies that are members of EFPIA,
- (22) The research activities should be covered by funding from the Community and at least on an equal level by resources from the research based pharmaceutical companies that are members of EFPIA. Further financing options may be available, inter alia, from the European Investment Bank, in particular through the Risk-Sharing Finance Facility developed jointly with the EIB and the Commission pursuant to Annex III of Council Decision on the Specific Programme "Cooperation".
- (23) The running costs of the IMI Joint Undertaking should be covered by equal amounts by EFPIA and the Community.
- (24) To ensure an equal partnership, the research based pharmaceutical companies that are members of EFPIA activities should not be eligible to receive financial support from the IMI Joint Undertaking.
- (25) The IMI Joint Undertaking should adopt, in accordance with Article 185(1) of Council Regulation 1605/2002¹⁰ and subject to prior consent of the Commission, specific financial rules 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

¹⁰ OJ L 248, 16.9.2002, p.1.

an efficient and timely manner. In order to ensure a harmonised treatment between the participants of the Joint Undertaking research activities and those of the indirect actions of the Seventh Framework Programme, it is appropriate that value added tax should not be an eligible cost for Community funding, in line with Regulation (EC) 1906/2006¹¹.

- (26) 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.
- (27) As a body possessing legal personality, the IMI Joint Undertaking should be accountable for its actions. As regards the resolution of disputes in contractual matters, it should be possible that the contracts concluded by the Joint Undertaking provide that the Court of Justice of the European Communities has jurisdiction.
- (28) Appropriate measures should be taken to prevent irregularities and fraud and the necessary steps should be taken to recover funds lost, wrongly paid or incorrectly used in accordance with Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests¹², Council Regulation (EC, Euratom) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities¹³, and the Regulation (EC) No 1073/1999 of the European Parliament and of the Council concerning investigations concluded by the European Anti-Fraud Office (OLAF)¹⁴.

¹¹ OJ L 391, 30.12.2006, p.1.

¹² OJ L 312, 23.12.1995, p.1.

¹³ OJ L 295, 15.11.1996, p.2.

¹⁴ OJ L 136, 31.05.1999, p.1.

- (29) In order to facilitate the setting up of the IMI Joint Undertaking, the Commission should be responsible for the establishment and initial operation of the IMI Joint Undertaking until it has the operational capacity to implement its own budget.
- (30) 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.
- (31) Since the objective of the action to be taken, namely the establishment of the IMI Joint Undertaking, cannot be sufficiently achieved by the Member States due to the trans-national nature of the great research challenge identified, which requires the pooling of complementary knowledge and financial resources across the sectors and borders and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve this objective.

HAS ADOPTED THIS REGULATION:

Article 1

Establishment of a Joint Undertaking

1. For the implementation of the Joint Technology Initiative on Innovative Medicines, a Joint Undertaking is hereby set up for a period up to 31 December 2017 (hereinafter referred to as "IMI Joint Undertaking").
2. The seat of the IMI Joint Undertaking shall be located in Brussels, Belgium.

Article 2

Objectives

The IMI Joint Undertaking shall contribute to the implementation of the Seventh Framework Programme and in particular the Theme 'Health' of the Specific Programme 'Cooperation' implementing the Seventh Framework Programme (2007-2013) of the European Community for research, technology development and demonstration activities. It shall have the objective of significantly improving the efficiency and effectiveness of the drug development process with the long-term aim that the pharmaceutical sector produce more effective and safer innovative medicines. In particular it shall:

- (a) support 'pre-competitive pharmaceutical research and development' in the Member States and countries associated to the Seventh Framework Programme via a coordinated approach to overcome the identified research bottlenecks in the drug development process;
- (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;
- (c) ensure complementarity with other activities of the Seventh Framework Programme;
- (d) be a public-private partnership aiming at increasing the research investment in the biopharmaceutical sector in the Members States and countries associated to the Seventh Framework Programme by pooling resources and fostering collaboration between the public and private sectors

- (e) to promote the involvement of SMEs in its activities, in line with the objectives of the Seventh Framework Programme.

Article 3

Legal status

1. The IMI Joint Undertaking shall be a Community body and shall have legal personality. In all the Member States of the European Community, it shall enjoy the most extensive legal capacity accorded to legal persons under the laws of those States. It may, in particular, acquire or dispose of movable and immovable property and be a party to legal proceedings.

Article 4

Statutes

The Statutes of the IMI Joint Undertaking, as set out in the Annex hereto, constitute an integral part of this Regulation and are hereby adopted.

Article 5

Community contribution

1. The maximum Community contribution to the IMI Joint Undertaking covering running costs and Research Activities shall be EUR 1000 million (one thousand million euros) paid from the budget appropriation allocated to the Theme 'Health' of the Specific Programme 'Cooperation' implementing the Seventh Framework Programme for research, technical development and demonstration (2007-2013) according to the provisions of Article 54(2)(b) of the Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities.

2. The arrangements for the Community financial contribution shall be established by means of a general agreement and annual financial agreements to be concluded between the Commission, on behalf of the Community, and the IMI Joint Undertaking.
3. The Community contribution to the IMI Joint Undertaking for the funding of the Research Activities shall be granted following open and competitive calls for proposals.

Article 6

Financial Regulation

1. The IMI Joint Undertakings shall adopt specific financial rules in accordance with Article 185(1) of Council Regulation 1605/2002¹⁵. They may depart from the framework Financial Regulation¹⁶ where the specific operating needs of the IMI Joint Undertaking so require and subject to prior consent of the Commission.
2. The IMI Joint Undertaking shall have its own internal audit capability.

Article 7

Staff

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 institutions of the European Communities for the purpose of applying these Staff Regulations and Conditions of Employment shall apply to the staff of the IMI Joint undertaking and its Executive Director.

¹⁵ OJ 248, 16.9.2002, p.1.

¹⁶ Commission Regulation (EC, Euratom) No2343/2002 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 on the Financial Regulation applicable to the budget of the European Communities, OJ L 357, 31.12.2002 p. 72; corrigendum in OJ L 2, 7.1.2003, p. 39.

2. Without prejudice to paragraph 3 and Article 6(3) of the Statutes, 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 in respect of its staff.
3. The Governing Board shall, in agreement with the Commission, adopt the necessary implementing measures referred to 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.
4. The staff resources shall be determined in the establishment plan of the IMI Joint Undertaking that will be set out in its annual budget.
5. The staff of the IMI Joint Undertaking shall consist of temporary agents and contract agents engaged for a fixed period that may be renewed no more than once for a fixed period. The total period of engagement shall not exceed seven years and shall not in any case exceed the lifetime of the Joint Undertaking.
6. All cost related to the staff shall be borne by the IMI Joint Undertaking.

Article 8

Privileges and Immunities

The Protocol on the Privileges and Immunities of the European Communities shall apply to the IMI Joint Undertaking and its staff.

Article 9

Liability

1. The contractual liability of the IMI Joint Undertaking shall be governed by the relevant contractual provisions and by the law applicable to the agreement or contract in question.
2. In the case of non-contractual liability, the IMI Joint Undertaking shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its staff in the performance of their duties.
3. Any payment by the IMI Joint Undertaking in respect of the liability referred to in paragraphs 1 and 2 and the costs and expenses incurred in connection therewith shall be considered as expenditure of the IMI Joint Undertaking and shall be covered by the resources of the IMI Joint Undertaking.
4. The IMI Joint Undertaking shall be solely responsible for meeting its obligations.

Article 10

Jurisdiction of the Court of Justice and applicable law

1. The Court of Justice shall have jurisdiction:
 - (a) in any dispute between the Members which relates to the subject matter of this Regulation and/or the Statutes referred to in Article 4;
 - (b) pursuant to any arbitration clause contained in agreements and contracts concluded by the IMI Joint Undertaking;
 - (c) in actions brought against the IMI Joint Undertaking, including decisions of its Bodies, under the conditions provided for in Articles 230 and 232 of the Treaty;

- (d) in disputes related to compensation for damage caused by the staff of the IMI Joint Undertaking in the performance of their duties.
2. For any matter not covered by this Regulation or by other acts of Community law, the law of the State where the seat of the IMI Joint Undertaking is located shall apply.

Article 11

Report, evaluation and discharge

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. This report shall contain details of implementation including number of proposals submitted, number of proposals selected for funding, type of participants, including SMEs, and country statistics.
2. By 3 years after the adoption of this Regulation but in any case no later than 31 December 2010, as well as by 31 December 2013, the Commission shall carry out an interim evaluation of the IMI Joint Undertaking with the assistance of independent experts on the basis of terms of reference established after consultation of the IMI Joint Undertaking. These evaluations 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 and, where appropriate, proposals to amend this Regulation, including the possible early termination of the IMI Joint Undertaking, to the European Parliament and the Council.
3. Not later than six months after the end of the Joint Undertaking, 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 to the European Parliament and to the Council.

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 rules of the IMI Joint Undertaking.

Article 12

Protection of the financial interests of the Members and anti-fraud measures

1. The IMI Joint Undertaking shall ensure that the financial interests of its Members are adequately protected by carrying out or by allowing the carrying out of appropriate internal and external controls.
2. In case of irregularities committed by the IMI Joint Undertaking or its staff, the Members shall reserve the right to recover amount unduly spent or to reduce or suspend any subsequent contribution to the IMI Joint Undertaking.
3. For the purposes of combating fraud, corruption and other illegal acts, Regulation (EC) No 1073/1999 shall apply.
4. The IMI Joint Undertaking shall carry out on-the-spot checks and financial audits among the participants of the Research Activities funded by the IMI Joint Undertaking.
5. The Commission and/or the Court of Auditors may, if necessary, carry out on-the-spot checks among the recipients of the IMI Joint Undertaking's funding and the agents responsible for allocating it. To that end, the IMI Joint Undertaking shall ensure that grant agreements and contracts provide for the right of the Commission and/or the Court of Auditors to carry out the appropriate controls and, in the event of the detection of irregularities, to impose dissuasive and proportionate penalties.

6. The European Anti-Fraud Office (OLAF) set up by Commission Decision 1999/352/EC, ECSC, Euratom shall enjoy the same powers in respect of the Joint Undertaking and its staff as it enjoys in respect of Commission departments. As soon as the Joint Undertaking is established it shall accede to the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council and the Commission regarding internal investigations by OLAF. The Joint Undertaking shall adopt the necessary measures needed to facilitate internal investigations conducted by OLAF.

Article 13

Confidentiality

Without prejudice to Article 14, the IMI Joint Undertaking shall ensure the protection of sensitive information, whose disclosure could damage the interests of its Members or of participants in the activities of the IMI Joint Undertaking.

Article 14

Transparency

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding access to European Parliament, Council and Commission documents¹⁷ shall apply to documents held by the IMI Joint Undertaking.
2. The IMI Joint Undertaking shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001 within six months after the entry into force of this Regulation.

¹⁷ OJ L 145, 31.5.2001, p. 43.

3. Decisions taken by the IMI Joint Undertaking pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice, under the conditions laid down in Articles 195 and 230 of the Treaty respectively.

Article 15

Intellectual property

The IMI Joint Undertaking shall adopt distinct rules governing the protection, use and dissemination of research results based on the principles of Regulation (EC) 1906/2006¹⁸ as set out in Article 22 of the Statutes which ensure that, where appropriate, intellectual property generated in Research Activities under this Regulation is protected, and that research results are used and disseminated.

Article 16

Preparatory actions

1. The Commission shall be responsible for the establishment and initial operation of the IMI Joint Undertaking until the Joint Undertaking has the operational capacity to implement its own budget. It shall carry out, in accordance with Community law, all necessary actions in collaboration with other Founding Members and the involvement of the Governing Board.
2. For that purpose, until such time as the Executive Director takes up his/her duties following his/her appointment by the Governing Board in accordance with Article 6(3) of the Statutes, the Commission may assign a limited number of its officials, including one to fulfil the functions of the Executive Director, on an interim basis.

¹⁸ OJ L 391, 30.12.2006, p.1.

3. The interim Executive Director may authorise all payments covered by the credits provided in the budget of the IMI Joint Undertaking once approved by the Governing Board and may conclude contracts, including staff contracts following the adoption of the IMI Joint Undertaking establishment plan. The Commission authorising officer may authorise all payments covered by the credits provided in the general budget of the IMI Joint Undertaking.

Article 17

Support from the host State

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.

Article 18

Entry into force

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Council

The President

STATUTES OF THE INNOVATIVE MEDICINES INITIATIVE JOINT UNDERTAKING

Article 1

Tasks and activities

The main tasks and activities of the IMI Joint Undertaking shall be the following:

- (a) to ensure the establishment and sustainable management of the Joint Technology Initiative on "Innovative Medicines";
- (b) to define and carry out the annual implementation plan referred to in Article 18 via calls for project;
- (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;
- (d) to mobilise the public and private sector resources needed;
- (e) to establish and develop close and long-term co-operation between the Community, industry and the other stakeholders such as regulatory bodies, patients organisations, academia and clinical centres, as well as cooperation between industry and academia;
- (f) to facilitate co-ordination with national and international activities in this area;
- (g) to undertake communication and dissemination activities;
- (h) to communicate and interact with the Member States and the countries associated to the Seventh Framework Programme via a group specifically established for this purpose, hereafter referred to as 'IMI States Representatives Group';

- (i) to organise at least 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;
- (j) to notify legal entities that have concluded a grant agreement, hereinafter referred to as Grant Agreement, with the IMI Joint Undertaking of the potential borrowing opportunities from the European Investment Bank, in particular the Risk Sharing Finance Facility set up under the Seventh Framework Programme.
- (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 per participant;
- (l) to ensure the efficiency of the Joint Technology Initiative on "Innovative Medicines";
- (m) to carry out any other activity needed to achieve the objectives referred to in Article 2 of this Regulation.

Article 2

Members

1. The founding members of the IMI Joint Undertaking, hereinafter referred to as "Founding Members", shall be:
 - (a) the European Community, represented by the Commission; and,
 - (b) upon acceptance of the Statutes of the IMI Joint Undertaking, the European Federation of Pharmaceutical Industries and Associations, hereinafter referred to as "EFPIA", a non-profit association registered under Swiss law (registration number 4749) with its permanent office in Brussels, Belgium. EFPIA operates as a representative organisation of the Pharmaceutical Industry in Europe.

2. Provided that they contribute to the funding to achieve the objectives of the IMI Joint Undertaking as described in Article 2 of this Regulation and accept the Statutes of the IMI Joint Undertaking, any legal entity supporting directly or indirectly research and development in a Member State or in a country associated to the Seventh Framework Programme may apply to become a Member of the IMI Joint Undertaking.
3. The Founding Members and new members referred to in paragraphs 1 and 2 are hereinafter referred to as "Members".

Article 3

Accession and changes to membership

1. Any application for new membership shall be addressed to the Governing Board.
2. Decisions of the Governing Board on accession of any other legal entity shall be made taking into account the relevance and potential added value of the applicant for the achievement of the objectives of the IMI Joint Undertaking. For any application for new membership, the Commission shall provide timely information to the Council on the assessment and, where applicable, on the decision of the Governing Board.
3. Any Member may terminate its membership of the IMI Joint Undertaking. The termination shall become effective and irrevocable six months after notification to the other Members following which the former Member shall be discharged from any obligations others than those approved by the IMI Joint Undertaking prior to the membership termination.

4. Membership of the IMI Joint Undertaking may not be transferred to a third party unless the prior agreement of the Governing Board is given.

Article 4

Bodies

1. The bodies IMI Joint Undertaking shall be:
 - the Governing Board,
 - the Executive Director,
 - the Scientific Committee.
2. In case a specific task is not assigned to one of the bodies, the Governing Board shall be the competent one.
3. The IMI Joint Undertaking shall be supported by two external advisory bodies: the IMI States Representatives Group and Stakeholder Forum.

Article 5

Governing Board

1. Composition and decision making process:
 - (a) each Member of the IMI Joint Undertaking shall be represented in the Governing Board by a maximum of five representatives;
 - (b) the Founding Members shall have five votes each in the Governing Board;
 - (c) 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;
 - (d) the vote of each Member shall be indivisible;

- (e) the Governing Board shall make decisions by a three-quarters majority and shall require the positive vote by the Founding Members;
- (f) the chairperson of the Governing Board shall be a representative of the Founding Members, serving on a rotating basis;
- (g) the representatives of the Members shall not be personally liable for actions undertaken in their capacity as representatives on the Governing Board.

2. The role and tasks

The Governing Board shall have overall responsibility for the operations of the IMI Joint Undertaking and shall oversee the implementation of its activities.

The Governing Board shall in particular:

- (a) assess the application(s) and decide changes in membership in accordance with Article 3;
- (b) decide on the termination of the membership in the IMI Joint Undertaking of any Member which does not fulfil its obligations without prejudice to the provisions of the Treaty ensuring compliance with Community law;
- (c) approve the Annual Implementation Plan proposal and the corresponding expenditure estimates;
- (d) approve the Annual Budget proposal, including the staff establishment plan;
- (e) approve the calls for proposals;
- (f) approve the Annual Activity Report, including the corresponding expenditure;
- (g) approve the Annual Accounts and the balance-sheet;
- (h) approve, as appropriate, any change to the Research Agenda recommended by the Scientific Committee;

- (i) approve the guidelines on evaluation and selection of project proposals as proposed by the Executive Office;
- (j) approve the list of selected project proposals;
- (k) appoint, dismiss or replace the Executive Director, provide guidance and direction to the Executive Director, and monitor the Executive Director's performance;
- (l) approve the organisational structure of the Executive Office based on recommendations of the Executive Director;
- (m) adopt the financial rules of the IMI Joint Undertaking in accordance with Article 6 of this Regulation;
- (n) approve the internal rules and procedures of the IMI Joint Undertaking, including the Intellectual Property Policy in line with the principles set out in Article 22;
- (o) adopt its rules of procedure in accordance with paragraph 3;
- (p) approve the initiatives to amend the Statutes in accordance with Article 23;
- (q) assign any task not specifically allocated to one of the other bodies of the IMI Joint Undertaking.
- (r) adopt practical arrangements for implementing Regulation (EC) No 1049/2001 as referred to in Article 14 of this Regulation;
- (s) Supervise the overall activities of the IMI Joint Undertaking.

3. Rules of procedure

- (a) The Governing Board shall meet at least twice a year. Extraordinary meetings shall be convened at the request of one of the Members or at the request of the Executive Director. The meetings shall normally take place at the seat of the IMI Joint Undertaking.

- (b) Unless otherwise decided in particular cases, the Executive Director shall participate in the meetings.
- (c) The chairman of the IMI States Representatives Group shall have the right to attend meetings of the Governing Board as an observer.
- (d) The chairman of the Scientific Committee shall participate by invitation of the Governing Board, as relevant to the agenda.
- (e) Observers and/or other experts may be invited by the Governing Board to attend meetings as and when relevant to the agenda.

Article 6

Executive Director

1. The Executive Director shall be the chief executive responsible for the day-to-day management of the IMI Joint Undertaking in accordance with the decisions of the Governing Board. In that context, he/she shall regularly inform as well as respond to any specific ad hoc requests for information from the Governing Board and the Scientific Committee. The Director shall exercise, in respect of the staff, the powers laid down in Article 7(2) of this Regulation.
2. The Executive Director shall be the legal representative of the IMI Joint Undertaking. He/she shall perform his/her tasks with complete independence, and shall be accountable to the Governing Board.

3. The Executive Director shall be appointed by the Governing Board for a period of three years following a call for expressions of interest published in the Official Journal of the European Union and in other periodicals or on internet sites. After an evaluation of the Director's performance, the Governing Board may extend the term of office once for a further period of not more than four years.

4. The Executive Director shall in particular:
 - (a) be responsible for the communication activities related to the IMI Joint Undertaking;
 - (b) manage appropriately the public and private funds
 - (c) recommend to the Governing Board, arrangements and guidelines for evaluation and selection of the project proposals for approval. These guidelines shall include procedures, composition, duties of the peer review committees that evaluate the project proposals and the rules for dissemination of research results;
 - (d) supervise the management of the launch of the calls for project proposals, the evaluation and selection of the project proposals, the negotiation of the selected project proposals, the follow-up of the project proposals and the administration of the grants, including the co-ordination of the funded research activities;
 - (e) be in charge of the establishment and management of the appropriate accounting system;
 - (f) provide the Governing Board and the Scientific Committee with relevant documentation and logistical support;
 - (g) prepare the annual implementation plan proposal and the corresponding expenditure estimates;

- (h) prepare the annual budget proposal, including the staff establishment plan;
- (i) prepare the annual activity report, including the corresponding expenditure;
- (j) prepare the annual accounts and the balance-sheet;
- (k) prepare any other information that may be requested by the Governing Board;
- (l) manage invitations for tenders for IMI Joint Undertaking goods/services requirements according to the financial rules of the IMI Joint Undertaking;
- (m) prepare the calls for proposals;
- (n) perform tasks entrusted or delegated to it by the Governing Board.
- (o) submit to the Governing Board any change to the Research Agenda as recommended by the Scientific Committee;
- (p) submit to the Governing 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;
- (q) convene meetings of the Governing Board;
- (r) call the annual meeting of the Stakeholder Forum, to ensure openness and transparency of the activities of the IMI Joint Undertaking with its stakeholders;
- (s) attend as appropriate the meetings of the Governing Board, of the Scientific Committee and of the Stakeholder Forum as observer;
- (t) if appropriate, set up scientific ad hoc/subsidiary bodies/committees decided by the Governing Board and gather experts scientific advice;
- (u) provide to the Governing Board any other information that may be requested;

- (v) be responsible for risk assessment and risk management;
- (w) propose to the Governing Board any insurance that it may be necessary for the IMI Joint Undertaking to take out in order to meet its obligations;
- (x) be responsible for concluding Grant Agreements for the implementation of the Research Activities, and service and supply contracts necessary for the operations of the IMI Joint Undertaking as referred to in Article 12.

5. The Executive Director shall be supported by the staff of the Executive Office.

Article 7

Scientific Committee

1. The Scientific Committee is an advisory body to the Governing Board and it shall conduct its activities in close liaison and with the support of the Executive Office.
2. The Scientific Committee shall consist of no more than 15 members.
3. The members shall reflect a balanced representation of expertise from academia, patient organisations, industry and regulatory bodies. Collectively, the Scientific Committee members shall have the scientific competencies and expertise covering the complete drug development process needed to make strategic science-based recommendations regarding the IMI Joint Undertaking.
4. The Governing Board shall establish the specific criteria and selection process for the composition of the Scientific Committee and shall appoint its members from a list proposed by the IMI States Representatives Group.

5. A chairperson shall be elected by consensus of the Scientific Committee from among its members.
6. The Scientific Committee shall have the following tasks:
 - (a) advise on the continued relevance of the Research Agenda and recommend any amendments;
 - (b) advise on the scientific priorities for the annual implementation plan proposal;
 - (c) advise the Governing Board and the Executive Director on the scientific achievements described in the annual activity report;
 - (d) advise on the composition of the peer review committees.
7. The Scientific Committee shall meet at least once a year and shall be convened by the chairperson.
8. The Scientific Committee may, with the agreement of the chairperson, invite non-member persons to participate in its meetings for advice.

Article 8

IMI States Representatives Group

1. Composition

The IMI States Representative Group shall consist of one representative of each Member State and of each country associated to the Framework Programme. It shall elect a chairperson among its members.

2. Role and tasks

The IMI States Representative Group shall have an advisory role for the IMI Joint Undertaking and shall act as an interface between the IMI Joint Undertaking and the relevant stakeholders within their respective countries. It shall in particular:

- a) advise on the annual scientific priorities, including the synergies with the Framework Programme;
- b) facilitate the dissemination of information related to the calls for stakeholders within their own countries;
- c) be informed on the outcome of the evaluation process;
- d) provide an opinion on the update of the Research Agenda;
- e) advise on the activities of the IMI Joint Undertaking;
- f) advise on the changes to the call and the evaluation process and intellectual property rules of the IMI Joint Undertaking;
- g) inform the IMI Joint Undertaking on relevant activities ongoing at national level;

3. The IMI States Representative Group shall meet at least bi-annually and shall be convened by the Executive Director. Extraordinary meetings can be convened to deal with specific matters of major relevance to IMI Joint Undertaking activities. These meetings shall be called by the Executive Director either on his/her own initiative or upon request from IMI States Representatives Group. The IMI States Representatives Group may issue, on its own initiative, recommendations to the IMI Joint Undertaking. The IMI Joint Undertaking shall inform the IMI States Representatives Group of the follow up it has given to such recommendations.

The Executive Director shall attend the meetings of the IMI States Representatives Group.

The IMI States Representative Group shall adopt its rules of procedure.

Article 9

Stakeholder Forum

1. The Stakeholder Forum shall be a meeting opened to all stakeholders and convened at least once a year by the Executive Director.
2. The Stakeholder Forum shall be informed on the activities of the IMI Joint Undertaking and shall be invited to provide comments.

Article 10

Internal Auditing function

The functions entrusted by Article 185(3) of Regulation (EC, Euratom) No 1605/2002 to the Commission's internal auditor shall be carried out under the responsibility of the Governing Board, which shall make appropriate provision taking into account the size and scope of the IMI Joint Undertaking.

Article 11

Sources of financing

1. All resources of the IMI Joint Undertaking and its activities shall be devoted to the objectives provided for in Article 2 of this Regulation.
2. The resources of the IMI Joint Undertaking entered to its budget shall be composed of:
 - (a) Members' financial contributions,
 - (b) any revenue generated by the IMI Joint Undertaking;
 - (c) any other financial contributions, resources and revenues.

Any interest yielded by the contributions paid by its Members shall be considered to be revenue of the IMI Joint Undertaking.

3. The running costs of the IMI Joint Undertaking shall be financed by its Members:
- (a) The Founding Members (Community and EFPIA) shall contribute on an equal level, each of them with an amount not exceeding 4% of the total financial contribution by the Community to the IMI Joint Undertaking. If part of the contribution from the Community is not used it may be available for Research Activities referred to in paragraph 4;
 - (b) Any other Member shall contribute in proportion to its total contribution towards the Research Activities.

4. The Research Activities shall be jointly funded through:

- (a) non-monetary contributions (hereinafter referred to as "contributions in kind") by the research based pharmaceutical companies that are members of EFPIA, with resources (such as personnel, equipment, consumables, etc.) at least equal to the financial contribution of the Community;
- (b) a matching financial contribution of the Community from the Seventh Framework Programme entered to the budget of the IMI Joint Undertaking;
- (c) contributions from Members referred to in Art 2(2).

Contributions in kind shall be subject to an evaluation. The methodology for evaluating contributions in kind shall be defined in the internal rules and procedures of the IMI Joint Undertaking, in compliance with its financial rules and based on the Rules of Participation of the Seventh Framework Programme. Contributions in kind shall be verified by an independent auditor.

5. The participating research based pharmaceutical companies that are members of EFPIA shall not be eligible to receive any financial support from the IMI Joint Undertaking for any activity.

6. Should any Member of the IMI Joint Undertaking, or any participating research based pharmaceutical company that is a member of EFPIA, fail to meet its commitments concerning its agreed contributions, the Executive Director shall convene a meeting of the Governing Board to decide:
 - (a) in the case of a defaulting Member, whether its membership should be terminated, or if any other measures should be taken until it has been met its obligations; or
 - (b) in the case of a defaulting participating research based pharmaceutical company that is a member of EFPIA, which appropriate measures should be taken.
7. The IMI Joint Undertaking shall own all assets generated by it or transferred to it for the fulfilment of its objectives provided for in Article 2 of this Regulation.

Article 12

Research activities, Grant Agreements and Project Agreements

1. The IMI Joint Undertaking shall support prospective research activities following open and competitive calls for project proposals, independent evaluation, and the conclusion of Grant Agreements and Project Agreements.
2. The IMI Joint Undertaking shall set up the procedures and mechanisms for the implementation, supervision and control of concluded Grant Agreements.

3. The Grant Agreement shall:
 - (a) set up the appropriate arrangements for the implementation of the research activities;
 - (b) set up the appropriate financial arrangements and the rules relating to intellectual property rights on the basis of the principles as set out in Article 22;
 - (c) govern the relationship between the selected consortium and the IMI Joint Undertaking.

4. The Project Agreement shall be concluded between the members of a consortium:
 - (a) to set up the appropriate arrangements for the implementation of the Grant Agreement;
 - (b) to govern the relationship between the participants in a project.

5. Any legal entity carrying out activities relevant to the objectives of the IMI Joint Undertaking in a Member State or country associated to the Seventh Framework Programme shall be eligible for participating in a project. Any other legal entities may participate if so agreed by the Governing Board.

6. Apart from the contribution to the running costs as set out in Article 11(3), the Community contribution to the IMI Joint Undertaking shall be used for the implementation of the Research Activities. The upper funding limits of such Community financial contribution shall comply with those laid down by the Rules for Participation of the Seventh Framework Programme. The following legal entities are eligible for such funding:

- (a) micro, small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC¹⁹;
- (b) legal entities established as non-profit public bodies under national law;²⁰
- (c) intergovernmental organisations, which have legal personality under international public law, as well as any specialised agencies set up by such intergovernmental organisations;
- (d) legal entities established under Community law;
- (e) legal entities established as non-profit organisations which carry out research or technological development as one of their main objectives;
- (f) secondary and higher education establishments;
- (g) non-profit qualified patients organisations.

7. In order to be considered eligible for Community funding, costs incurred in the implementation of the research activities shall be exclusive of value added tax.

Article 13

Financial commitments

The financial commitments of the IMI Joint Undertaking shall not exceed the amount of financial resources available or committed to its budget by its Members.

¹⁹ O J L 124, 20.2003, p.36.

²⁰ For the purpose of this Regulation, "non-profit public bodies" include those that may make profit but are not permitted to distribute such profits otherwise than in the furtherance of public interest purposes and which carry out scientific and technological research among their main activities.

Article 14

Financial revenues

Except when the IMI Joint Undertaking is wound up pursuant to Article 24, any excess revenue over expenditure shall not be paid to the Members of the IMI Joint Undertaking.

Article 15

Financial year

The financial year shall correspond to the calendar year.

Article 16

Financial implementation

The Executive Director shall implement the budget of the IMI Joint Undertaking.

Article 17

Financial reporting

1. Every year, the Executive Director shall present to the Governing Board a preliminary draft Annual Budget Plan containing a forecast of annual expenditure for the following two years. Within this forecast, the estimates of revenue and expenditure for the first of those two years shall be drawn up in such detail as is necessary for the internal budgetary procedure of each Member regarding its financial contributions to the IMI Joint Undertaking. The Executive Director shall supply the Governing Board with all supplementary information needed for this purpose.
2. The members of the Governing Board shall communicate to the Executive Director their comments on the preliminary draft Annual Budget Plan and in particular on the estimates of resources and expenditure for the following year.
3. Taking into account the comments received from the members of the Governing Board, the Executive Director shall prepare the draft Annual Budget Plan for the following year and submit it to the Governing Board for approval.

4. The Annual Budget Plan and the annual implementation plan for a particular year shall be adopted by the Governing Board of the IMI Joint Undertaking by the end of the previous year.
5. Within two months after the closure of each financial year, the annual accounts and balance sheets for the preceding year shall be submitted by the Executive Director to the Governing Board for approval. The Annual Accounts and balance sheets for the preceding year shall be submitted to the Court of Auditors and the Commission.

Article 18

Planning and reporting

1. The Annual Implementation Plan shall describe the activities of IMI Joint Undertaking planned for the coming year and the corresponding expenditure estimates. Once approved by the Governing Board, a publishable version of the Annual Implementation Plan shall be made publicly available.
2. An Annual Activity Report shall present progress made by the IMI Joint Undertaking in each calendar year, in particular in relation to the Annual Implementation Plan for that year. It shall also include information on the performed Research Activities and the participation of SMEs in them as well as on other activities during the previous year and the corresponding expenditure. The expenditure shall be based on Members' financial contributions as well as contributions from participating research based pharmaceutical companies that are members of EFPIA.

The Annual Activity Report shall be presented by the Executive Director together with the Annual Accounts and balance sheets. Once approved by the Governing Board, the Annual Activity Report shall be made public.

Article 19

Service and supply contracts

The IMI Joint Undertaking shall set up all the procedures and mechanisms for the implementation, supervision and control of concluded service and supply contracts concluded where necessary for the operations of the IMI Joint Undertaking, according to the provisions of its financial rules.

Article 20

Liability of Members, Insurance

1. The financial liability of the Members for the debts of the IMI Joint Undertaking is limited to their contribution already made for the running costs as set out in Article 11(3).
2. The IMI Joint Undertaking shall take out and maintain appropriate insurance.

Article 21

Conflict of Interests

The IMI Joint Undertaking shall avoid any conflict of interest in the implementation of its activities.

Article 22

Intellectual Property Rights policy

1. The IMI Joint Undertaking shall adopt its general rules governing the intellectual property policy of the IMI Joint Undertaking that will be incorporated in the Grant Agreements and Project Agreements.

2. The objective of the intellectual property policy of the IMI Joint Undertaking is to promote knowledge creation, together with its disclosure and exploitation, to achieve fair allocation of rights, to reward innovation, and to achieve a broad participation of private and public entities (including, but not limited to, participating research based pharmaceutical companies that are members of EFPIA, academic groups and small and medium-sized enterprises) in projects.
3. The Intellectual Property policy shall reflect the following principles:
 - (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 in writing 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.
 - (b) Participants in a project shall undertake to disseminate and allow the use of the results and the intellectual property generated by the project concerned under terms and conditions defined in the Grant Agreement and the Project Agreement taking into account the protection of intellectual property rights, confidentiality obligations and legitimate interests of the owners.

Article 23

Amendments to the Statutes

1. Any Member of the IMI Joint Undertaking may take an initiative to the Governing Board for the amendment of these Statutes.

2. The initiatives referred to in paragraph 1 as approved by the Governing Board shall be submitted as draft amendments to the Commission who shall adopt them, as appropriate.
3. However, any amendment affecting the essential elements of these Statutes and in particular amendments to Articles 2, 3, 5, 6, 11, 12, 20, 23 and 24 shall be adopted in accordance with Article 172 of the Treaty.

Article 24

Winding up

1. At the end of the period provided for in Article 1 of this Regulation, or following an amendment pursuant to Article 11(2) to this Regulation, the IMI Joint Undertaking shall be wound up.
2. The winding up procedure shall be automatically triggered if one of the Founding Members terminates its membership of the IMI Joint Undertaking.
3. For the purpose of conducting the proceedings in winding up of the IMI Joint Undertaking, the Governing Board shall appoint one or more liquidators, who shall comply with the decisions of the Governing Board.
4. When the IMI Joint Undertaking is being wound up, it shall return to the host state any physical support item made available by the host state in accordance with the host agreement.
5. When any physical support item has been dealt with as provided in paragraph 4, any further assets shall be used to cover the liabilities of the IMI Joint Undertaking and the expenditures relating to its winding up. Any surplus or deficit shall be distributed among or met by the Members existing at the time of the winding up in proportion of their actual contribution to the IMI Joint Undertaking. Any surplus distributed to the Community shall be returned to the Commission budget.

6. Remaining assets, debts or liabilities shall be distributed to the Members existing at the time of the winding up in proportion to their actual contribution to the IMI Joint Undertaking.
 7. An *ad hoc* procedure shall be set up to ensure the appropriate management of any Grant Agreement referred to in Article 12 and service and supply contract referred to in Article 19, with duration longer than the duration of the IMI Joint Undertaking.
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