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PROPOSAL

from:	Commission
dated:	16 May 2007
Subject:	Proposal for a Council Regulation setting up the Innovative Medicines Initiative Joint Undertaking

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU to Mr Javier SOLANA, Secretary-General/High Representative.

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Encl.: COM(2007) 241

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15.5.2007
COM(2007) 241 final

2007/0089 (CNS)

Proposal for a

COUNCIL REGULATION

setting up the Innovative Medicines Initiative Joint Undertaking

(presented by the Commission)

[SEC(2007) 568]
[SEC(2007) 569]

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Grounds for and objectives of the proposed Innovative Medicines Initiative Joint Undertaking

Joint Technology Initiatives (JTIs) are introduced in the Seventh Framework Programme[1] (FP7) as a new way of realising public-private partnerships in research at European level. JTIs are an expression of the EU's strong commitment to coordinating research efforts, so contributing to the realisation of the European Research Area and Europe's competitiveness goals.

JTIs arise primarily from the work of European Technology Platforms (ETPs). In a small number of cases, ETPs have achieved such an ambitious scale and scope that they will require the mobilisation of high public and private investments as well as substantial research resources to implement important elements of their Strategic Research Agendas. JTIs are proposed as an effective means of meeting the needs of this small number of ETPs.

In the Co-operation Specific Programme[2] 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).** This initiative will strengthen Europe’s position in pharmaceutical research. It will re-invigorate the European pharmaceutical sector, make Europe more attractive to research investment and, in the long term provide European citizens with faster access to better medicines.

Drug development is a very long and costly process. Having once been world leader in pharmaceutical research, Europe is now lagging in research investment, both public and private. The IMI JTI aims to improve this situation by a unique collaboration in the pharmaceutical sector. For the first time, competitor pharmaceutical companies will collaborate on research to improve the drug development process. Participation of academia and clinical centres, small and medium sized enterprises (SMEs), patient organisations and public authorities (including regulators) will be essential and will lead to faster uptake of results. Traditional EU collaborative research instruments cannot achieve the co-ordination of research efforts necessary to cope with the scale and complexity of the research challenges involved.

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1 OJ L 412, 30.12.2006, p.1

2 OJ L 400, 30.12.2006, p. 66-241

Competencies and resources from the private and the public sectors will be pooled in a public-private partnership to be founded as a Joint Undertaking by the European Commission (EC) and EFPIA (the European Federation of Pharmaceutical Industries and Association). The IMI JU will be set up as a Community body by a Council Regulation under Article 171 of the Treaty. It will have a total budget of EUR 2 billion. The EC will contribute with EUR1 billion from FP7. The other EUR1 billion will be contributed by EFPIA and the research-based pharmaceutical companies that are full members of EFPIA.

The IMI JU will support research activities conducted in the Member States and in the countries associated with FP7, following open calls for proposals. The Community contribution will be used exclusively to support academia and clinical centres, SMEs, patient organisations and public authorities (including regulators). The EFPIA member companies will carry the costs of their part of the research collaboration at a value equal to the Community contribution.

General Context

The pharmaceutical industry is important for the knowledge based economy. As a research-intensive sector, it contributes significantly to European innovation climate and economy. Investing around 15% of its turnover in research and development, it provides Europe with high-skill jobs (612,000 employees in 2004, of which 103,000 in research), high-value products, crucial to the health and well-being of European citizens, and benefits other economic sectors.

The impact of pharmaceutical sector to the economy is often discussed only in terms of costs to the public health system. However, it should be stressed that innovative medicines produce considerable economic benefits including:

- increased total economic production value (e.g. avoiding temporary disabilities, or decreasing their length),
- reinforced employment, through research, production, and distribution of innovative medications,
- added value through highly trained people,
- eased burden on public health (e.g. reducing hospital stays), and on pension systems (e.g. avoiding early pension eligibility),
- increased quality of life (e.g. reduced morbidity and mortality).

IMI addresses the issue of Europe's relative decline in pharmaceutical research by focussing on the main challenges to:

– improve prediction of the safety and the efficacy of new drug candidates in the early development phases, before the costly clinical trials begin;

– tackle the current multiplication of research efforts, both in the private and public sector, by jointly developed knowledge management systems;

– bridge gaps in training of professionals to ensure a more skilled workforce in Europe for this sector.

In addition, IMI will serve as a focal point to for developing synergies between research and collaboration with national, European and international activities and will contribute to establishing the European Research Area in this sector.

A paradigm shift in collaborative patterns will be necessary to meet these challenges. Traditionally, pharmaceutical companies work on a one-to-one basis with partners such as universities, SMEs to develop new drugs. The present challenges demand research and development on tools and methodologies that can be used by all companies active in the drug development process. Today industry investment in such research is very low, and collaboration between these highly competitive companies is rare. In addition, industry does not have all the necessary competencies to carry out this complex research alone. This is why a new approach at European level is needed, with academia and clinical centres, SMEs, patient organisations, public authorities (including regulators) working together with industry.

EFPIA, a non-profit organization representing the research-based pharmaceutical industry in Europe, took the lead in setting up the ETP on Innovative Medicines. Following consultation with a wide spectrum of stakeholders, the Innovative Medicines ETP developed a Strategic Research Agenda (SRA) detailing the challenges discussed above and ways to tackle them. The European Commission brought together representatives from the Member States and from the Countries associated to FP6. This group has met regularly and has actively supported the ETP by providing constructive comments, ideas and experiences based on national activities in the area.

The JTI is the most appropriate means of co-ordinating efforts given the scale and complexity of the research challenges. Therefore, the Commission proposed the implementation of the SRA on Innovative Medicines as a JTI in its proposal for FP7 confirmed through the co-decision by the Council and the European Parliament.

The proposed governance structure for the IMI JTI, which has been developed though a close collaboration between the Commission and EFPIA clearly reflects the public-private nature of the initiative. In their role as founders, the Commission and EFPIA will equally share the responsibilities and costs for the implementation of the IMI JTI. It will be governed by the IMI JU (Board, Executive Office and Scientific Committee) and by 2 additional groups (Member States Group and Stakeholder Forum).

The IMI JU will manage the implementation of the research activities outlined in the Research Agenda. The Executive Office, with its independent staff, will be responsible for the day-to-day management, including the call and evaluation process, grant agreements, etc. The Board, composed of the founding members, will have overall responsibility for the operations of the IMI JU, and decide on the annual implementation of the research activities following consultation of the Scientific Committee. It will also be responsible for communication and co-ordination between IMI and Member State activities (via the Member States Group). A Stakeholder Forum will be held annually to exchange views on the ongoing or planned research activities.

The research activities will be conducted through collaborative projects between public and private organisations selected though open calls for proposals and a peer review process. Any legal entity can participate in such projects provided the research is done in Member States or in the countries associated with FP7.

The research activities will be financed through contributions: with resources 'in kind' (personnel, equipment, consumables, etc.) from the EFPIA member companies and with financial support for universities, public research organisations, SMEs, patient organisations etc. from the EC Contribution to IMI JU. All participating for-profit organisations that are not considered as SMEs are expected to carry the costs of participation in the research activities and will not receive any financial support from the IMI JU.

Grant agreements will govern the relationship between the selected consortia and the IMI JU. Such agreements will describe the implementation of the research activities, the appropriate financial arrangements and the rules relating to intellectual property rights on, the basis of the principles as set out in the Statutes of the IMI JU.

The intellectual property policy for IMI JU designed to be beneficial to the different participants: pharmaceutical companies want to have access to new methods and results; SMEs want to have their new techniques tested by users (i.e. pharmaceutical companies); universities want their research results validated and recognised; clinicians want to have rapid access to results and data; patients want more efficient medicines with less side effects, etc. The new collaborative partnership of IMI JU will provide legal and operational framework for a win-win situation for all. It should ensure the maximum utilization of research results and data, and rapid uptake into industrial, clinical and regulatory practice.

Through revitalisation of research in the pharmaceutical sector, Europe should become an attractive and dynamic environment for private investment.

Existing provisions in the area of the proposal

No provisions exist today at a European level in this area.

However, the FP6-funded Integrated Project InnoMed (involving 43 partners, including 18 large pharmaceutical companies) serves as evidence of industry's willingness to cooperate with each other and with other stakeholders.

Consistency with other Union policies and objectives

The proposed Regulation is consistent with Community policies in research. It is also consistent with the renewed Lisbon strategy[3] and the objectives of the EU to invest 3% of its GDP in research and development by 2010, with two-thirds coming from the private sector, as decided by the European Council in Barcelona 2002. The proposal is also consistent with the objectives of the previous G10 process[4] on public health and EU Pharmaceuticals policies, the ongoing policy reflection process of the

[3] COM (2005) 24

[4] COM (2003) 383

EU Pharmaceutical Forum, and to the recent Aho report "Creating an Innovative Europe"[5].

The proposed initiative is part of a broad ambitious Community strategy aimed at tackling the innovation gap which includes, inter alia, the proposal to establish a European Institute of Technology.

2. CONSULTATION AND IMPACT ASSESSMENT

Consultation of interested parties and use of expertise

Stakeholders (pharmaceutical industry, academia and clinical centres, SMEs, patient organisations, public authorities (including regulators)) have been widely consulted. The key forum for discussion with representatives of the Member States has been the IMI Member States Contact Group. The European Medicines Evaluation Agency (EMEA) has contributed through consultations of their scientific committees. In addition, comments have been received following the publication of the draft SRA on the web and presentations at European and International level.

Impact assessment

The proposed Regulation has been subject to a Commission Impact Assessment, which is attached to the proposal.

3. LEGAL FRAMEWORK OF THE PROPOSAL

Summary of the proposed action

The present proposal concerns setting up the Innovative Medicines Initiative Joint Undertaking (IMI JU) under Article 171 of the Treaty for the implementation of the Joint Technology Initiative on Innovative Medicines (IMI JTI).

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.

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 of the European Community.

The IMI JU will be open to new members, provided that they contribute with funds to achieve its objectives.

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[5] Aho, Jozef Cornu, Luke Georghiou and Antoni Subriá: "Creating an Innovative Europe", Jan. 2006

The European Commission will be represented on the Board. Any decision by the Board shall require the positive vote of the European Commission.

Legal basis

The legal basis of the proposal is Article 171 of the Treaty establishing the European Community.

Subsidiarity and Proportionality

The proposal concerns an area in which the Community does not have exclusive competence, which is why the principle of subsidiarity applies.

The policy objective underlying the proposal can only be achieved through Community action and this for the following reasons:

(1) The trans-national nature of the great research challenge identified, which requires the pooling of complementary knowledge and financial resources across sectors and borders. No single Member State, company or stakeholder can in and by itself resolve the problem.

(2) The co-ordination effort and the resources required are of such a large scale that they can only be credibly implemented at European level.

(3) In view of similar and competing initiatives being launched in other leading economies (e.g. Critical Path Initiative in the US), only a large-scale action implemented at European level is sufficiently attractive for the globally acting pharmaceutical industry.

In accordance with the principle of proportionality, the provisions of this regulation do not go beyond what is necessary to achieve its objectives.

Choice of instrument

The proposed Regulation will boost the public and private investment in research aiming at improving the competitiveness of the European pharmaceutical sector. The Joint Undertaking option offers a potential leverage effect of Community funds with private resources that cannot be achieved with the traditional instruments of the Framework Programme, i.e. each EUR 1 of Community funds will generate research investments worth at least EUR 2.

Increased research investments will stimulate further investments in other industrial sectors. In addition, more public funds will be available for non profit stakeholders in the research activities, and the total research investment is expected to be higher than with the traditional EU collaborative research scheme.

4. BUDGETARY IMPLICATIONS

The total budget of the IMI JU will be EUR 2 billion.

The maximum contribution from the European Community will be EUR 1 billion paid from the budget appropriation allocated to the Theme 'Health' of the Specific Programme 'Cooperation' implementing FP7.

The running costs of the IMI JU will be financed in equal parts by EFPIA and the European Community. The running costs will not exceed 4% of the total budget for the period ending on 31.12.2017.

The Research Activities will be jointly funded through a financial contribution of the European Community, and contributions by the research based pharmaceutical companies that are full members of EFPIA, with resources in kind (such as personnel, equipment, consumables, etc.) at least equal to the financial contribution of the European Community.

5. ADDITIONAL INFORMATION

Transitory period

In order to facilitate the setting up of the IMI JU, the Founding Members, the EC and EFPIA, should take all necessary preparatory actions until the bodies responsible for its operations have been set up.

Review

The EC will present an annual report on the progress achieved by the IMI JU

Discharge for the implementation of the budget of the IMI JU will be given by the European Parliament, upon 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.

2007/0089 (CNS)

Proposal for a

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 Commission[6],

Having regard to the opinion of the European Parliament[7],

Having regard to the opinion of the European Economic and Social Committee[8],

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)[9] 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 to 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)[10] (hereinafter referred as the "Specific Programme Cooperation"), underlines the need for ambitious pan-European public private

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6 OJ C, , p. .
7 Opinion of the European Parliament of (…)
8 Opinion delivered on (…)
9 OJ L 412, 30.12.2006, p.1
10 OJ L 400, 30.12.2006, p. 86. Corrected version in OJ L 54, 22.2.2007 p. 30.

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) 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 Plans[11], 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”,

(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"[12] 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)”[13],

(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, increase

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11 COM(2003) 226 final

12 COM (2003)383

13 COM(2002)27

the competitiveness of Europe and help to establish Europe as the most attractive place for biopharmaceutical research and development.

(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".

(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 though 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 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).

(15) The IMI Joint Undertaking, which should be responsible for the implementation of Joint Technology Initiative on "Innovative Medicines", and discharge commitments pursuant to international agreements, should be considered as an international body within the meaning of Article 22 of Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal service sectors[14], and Article 15 of Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts[15].

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[14] OJ L 134, 30.4.2004, p.1. Directive as last amended by Directive 2006/97/EC (OJ L 363,20.12.2006, p.107)

[15] OJ L 134, 30.4.2004, p.1. Directive as last amended by Directive 2006/97/EC

(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[16], 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.

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

(18) 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 full 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.

(19) 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.

(20) Switzerland is foreseen to become a country associated to the Seventh Framework Programme via the signature of an Association Agreement with the Community.

(21) The IMI Joint Undertaking should be open to new members.

(22) The rules for organisation and operation of the IMI Joint Undertaking should be laid down in the Statutes of the IMI Joint Undertaking.

(23) 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 full members of EFPIA,

(24) 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 full members of EFPIA.

(25) The running costs of the IMI Joint Undertaking should be covered by equal amounts by EFPIA and the Community.

(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.

(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

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[16] 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, 7.12003, p. 39

financial regulation[17] 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.

(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.

(29) Taking into account that the IMI Joint Undertaking is not designed to fulfil an economic purpose and is responsible for managing the Joint Technology Initiative on "Innovative Medicines", it is necessary for the performance of its tasks that the Protocol on the Privileges and Immunities of the European Communities of 8 April 1965 should apply to the IMI Joint Undertaking and its staff.

(30) 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.

(31) 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 interests[18], 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 irregularities[19], and the Regulation (EC) No1073/1999 of the European Parliament and of the Council concerning investigations concluded by the European Anti-Fraud Office (OLAF)[20].

(32) In order to facilitate the setting up of the IMI Joint Undertaking, the founding members should take all necessary preparatory actions until the bodies responsible for its operation has been set up,

(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.

(34) 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-

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17 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, 7.12003, p. 39

18 OJ L 312,23.12.1995, p.1

19 OJ L 295,15.11.1996, p.2

20 OJ L 136,31.05.1999, p.1

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 by reason of co-ordination effort and the resources required are such large scale, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set our 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 ending on 31 December 2017 (hereinafter referred to as "IMI Joint Undertaking"). This period may be extended by the Council.

2. The seat of the IMI Joint Undertaking shall be located in Brussels, Belgium.

Article 2
Legal status

1. The IMI Joint Undertaking shall have legal personality. In the Member States, 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.

2. The IMI Joint Undertaking shall be considered as an international body within the meaning of point c of Article 22 of Directive 2004/17/EC and of point c of Article 15 of Directive 2004/18/EC.

Article 3
Objectives

The IMI Joint Undertaking shall contribute to the implementation of the Seventh Framework Programme and 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, and, in particular to:

(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) 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;

(d) conclude service and supply contracts necessary for the operations of the IMI Joint Undertaking;

(e) ensure the efficiency and durability of the Joint Technology Initiative on "Innovative Medicines".

Article 4
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;

(b) the European Federation of Pharmaceutical Industries and Associations (hereinafter referred to as “EFPIA”).

2. Provided that they contribute to the funding to achieve the objectives of the IMI Joint Undertaking as provided for in Article 3, the following may apply to become a member of the IMI Joint Undertaking:

(a) Member States and countries associated to the Seventh Framework Programme;

(b) Any legal entity supporting directly or indirectly research and development in the Members States and countries associated to the Seventh Framework Programme.

3. The Founding Members and new members as referred to in paragraphs 1 and 2 are hereinafter referred to as "Members".

Article 5
Statutes

The Statutes of the IMI Joint Undertaking are set out in the Annex.

Article 6
Sources of financing

1. The IMI Joint Undertaking and its activities shall be jointly funded through contributions from its Members.

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.

3. The operational costs, hereinafter referred to as the Research Activities, shall be jointly funded through financial contribution of the Community and voluntary contributions by the research based pharmaceutical companies that are full members of EFPIA with resources at least equal to the Community contribution.

4. The maximum Community contribution to the IMI Joint Undertaking covering running costs and Research Activities shall be EUR 1 billion (one billion 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.

5. 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.

Article 7
Eligibility for funding

The Community contribution to the IMI Joint Undertaking for the funding of the Research Activities shall be granted following competitive calls for proposals. The following legal entities shall be eligible for such funding:

(a) micro, small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC[21];

(b) legal entities established as non-profit public bodies under national law;

(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) qualified non-profit patients organisations.

[21] OJ L 124, 20.5.2003, p. 36

Article 8
Financial Regulation

1. The IMI Joint Undertaking's Financial Regulation shall be based on the principles of the Framework Financial Regulation[22]. 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.

2. The IMI Joint Undertaking shall have its own internal audit capability.

Article 9
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 European Community institutions 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.

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.

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.

Article 10
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 11
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.

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[22] OJ L 357, 31.12.2002 p. 72; corrigendum in OJ L 2, 7.12003, p. 39

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.

Article 12
Jurisdiction of the Court of Justice and applicable law

1. The Court of Justice shall have jurisdiction in any dispute between the Members which relates to the subject matter of this Regulation and the Statutes referred to in Article 5 of this Regulation.

2. The Court of Justice shall have jurisdiction to give judgment pursuant to any arbitration clause contained in agreement and contract concluded by the IMI Joint Undertaking.

3. The Court of Justice shall have jurisdiction in actions brought against the IMI Joint Undertaking, including decisions of its Board, under the conditions provided for in Articles 230 and 232 of the Treaty.

4. The Court of Justice shall have jurisdiction in disputes relating to compensation for damage caused by the staff of the IMI Joint Undertaking in the performance of their duties.

5. 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 13
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.

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.

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.

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.

Article 14
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 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, on behalf of the IMI Joint Undertaking, the appropriate controls and, in the event of the detection of irregularities, to impose dissuasive and proportionate penalties.

5. 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 approve that accession and adopt the necessary measures needed to facilitate internal investigations conducted by OLAF.

Article 15
Confidentiality

The IMI Joint Undertaking shall ensure the protection of sensitive information, disclosure of which could damage the interests of its Members.

Article 16
Intellectual property

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.

Article 17
Preparatory actions

The Founding Members shall be responsible for carrying out all activities relating to the establishment of the IMI Joint Undertaking until the bodies responsible for its operation have been set up.

Article 18
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 19
Entry into force

This Regulation shall enter into force on the third day of 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

ANNEX

STATUTES OF THE INNOVATIVE MEDICINES INITIATIVE JOINT UNDERTAKING

Article 1
Name, location, duration and legal personality

1. The name of the Joint Undertaking shall be: “Innovative Medicines Initiative Joint Undertaking", hereinafter referred to as IMI Joint Undertaking.

2. Its seat shall be located in Brussels, Belgium.

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.

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.

5. The IMI Joint Undertaking shall have legal personality. In all the Member States, 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 2
Objectives and main tasks

1. The objectives of the IMI Joint Undertaking shall be to contribute to the implementation of the Seventh Framework Programme of the European Community for research, technology development and demonstration activities (2007-2013), hereinafter referred to as the 'Seventh Framework Programme', and 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, and, in particular:

   (a) to support 'pre-competitive pharmaceutical research and development', i.e. research on the tools and methodologies used in the drug development process 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) to 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) to be a public-private partnership aiming at increasing the research investment in the biopharmaceutical sector in the Member States and countries associated to the Seventh Framework Programme by pooling resources and fostering collaboration between the public and private sectors;

(d) to conclude service and supply contracts necessary for the operations of the IMI Joint Undertaking;

(e) to ensure the efficiency and durability of the Joint Technology Initiative on "Innovative Medicines".

2. The main tasks 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 manage the annual implementation plan referred to in Article 13 via calls for project proposals open to legal entities worldwide provided that their Research Activities will be prospective and carried out in a Members State or a country associated to the Seventh Framework Programme unless otherwise agreed on an exceptional basis;

(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;

(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;

(f) to facilitate co-ordination with national and international activities in this area;

(g) to manage communication and dissemination of the activities of the IMI Joint Undertaking subject to confidentiality obligations;

(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 Member States Group';

(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;

(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.

Article 3
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;

   (b) 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(1), the following may apply to become a Member of the IMI Joint Undertaking:

   (a) Member States and countries associated to the Seventh Framework Programme;

   (b) any legal entity supporting directly or indirectly research and development in a Member State or a country associated to the Seventh Framework Programme.

3. The Founding Members and new members referred to in paragraphs 1 and 2 are hereinafter referred to as "Members".

4. Any application for new membership shall be addressed to the Board in accordance with Article 5.

5. 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.

Article 4
Bodies

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

Article 5
Board

1. Composition and decision making process of the Board shall be the following:

(a) the Founding Members shall have five votes each in the Board;

(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;

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

(d) the Board shall make decisions by a three-quarters majority and shall require the positive vote by the Founding Members;

(e) each Member of the IMI Joint Undertaking shall be represented in the Board by a maximum of five representatives;

(f) the chairperson of the 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 Board.

2. The role and tasks of the Board shall be the following;

(a) the Board shall have overall responsibility for the operations of the IMI Joint Undertaking;

(b) the Board shall oversee the implementation of the IMI Joint Undertaking activities;

(c) the Board shall in particular:

– assess the application(s) for any new membership to the IMI Joint Undertaking. Any application of a Member State or a country associated to the Seventh Framework Programme or an international organisation shall be subject to approval by the Council. Any other applications shall be decided by the Board;

– decide on the termination of the membership in the IMI Joint Undertaking of any Member which does not fulfil its obligations notwithstanding the provisions of the Treaty ensuring compliance with Community law;

– approve the annual implementation plan proposal and the corresponding expenditure estimates;

– approve the annual budget proposal, including the staff establishment plan;

– approve the annual activity report, including the corresponding expenditure;

– approve the annual accounts and the balance-sheet;

– arrange for the establishment of the internal audit capabilities of the IMI Joint undertaking;

– approve any change to the Research Agenda as recommended by the Scientific Committee;

– 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 internal rules and procedures of the IMI Joint Undertaking, including the Intellectual Property Policy;

– approve the staff regulation of the IMI Joint Undertaking in accordance with Article 14;

– adopt the Board procedures;

– agree on proposed amendments of the IMI Joint Undertaking's Statutes in accordance with Article 21;

– assign any task which is not specifically allocated to one of the bodies of the IMI Joint Undertaking.

3. The 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 Head Office of the IMI Joint Undertaking.

(a) Unless otherwise decided in particular cases, the Executive Director shall participate in the meetings.

(b) The chairman of the Scientific Committee shall participate by invitation of the Board, as relevant to the agenda.

(c) Observers and/or other experts may be invited by the Board to attend meetings as and when relevant to the agenda.

Article 6
Executive Office

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

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;

   (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:

   – recommend to the 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;

   – manage 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;

   – be in charge of the establishment and management of the appropriate accounting system;

   – provide the Board and the Scientific Committee with relevant documentation and logistical support;

   – prepare the annual implementation plan proposal and the corresponding expenditure estimates;

   – prepare the annual budget proposal, including the staff establishment plan;

   – prepare the annual activity report, including the corresponding expenditure;

   – prepare the annual accounts and the balance-sheet;

   – prepare any other information that may be requested by the Board;

– manage invitations for tenders for IMI Joint Undertaking goods/services requirements according to the financial regulation of the IMI Joint Undertaking;

– perform tasks entrusted or delegated to it by the Board.

3. 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 Board. In that context, he/she shall regularly inform as well as respond to any specific ad hoc requests for information from the Board and the Scientific Committee.

4. The Executive Director shall be the chief executive responsible for the day-to-day management of the IMI Joint Undertaking and be its legal representative. He/she shall perform his/her tasks with independence, and shall be accountable to the Board.

5. The Executive Director shall be appointed by the Board, from a list of candidates proposed by the Commission, for a period of up to three years. After an evaluation of the Director's performance, the Board may extend the term of office once for a further period of not more than four years.

6. The Executive Director shall direct the activities of the IMI Joint Undertaking in accordance with the decisions of the Board. In that context, he/she shall regularly inform as well as respond to any specific ad hoc requests for information from the Board and the Scientific Committee.

7. The Executive Director shall in particular:

(a) submit to the Board the annual implementation plan proposal and the corresponding expenditure estimates;

(b) submit to the Board the annual budget proposal, including the staff establishment plan;

(c) submit to the Board the annual activity report, including the corresponding expenditure;

(d) submit to the Board the annual accounts and the balance-sheet;

(e) submit to the Board any change to the Research Agenda as recommended by the Scientific Committee;

(f) supervise the management of the calls for project proposals;

(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;

(h) convene meetings of the Board;

(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;

(j) attend as appropriate the meetings of the Board, of the Scientific Committee and of the Stakeholder Forum as observer;

(k) if appropriate, set up scientific ad hoc/subsidiary bodies/committees decided by the Board and gather experts scientific advice;

(l) provide to the Board any other information that may be requested;

(m) be responsible for risk assessment and risk management;

(n) propose to the Board any insurance that it may be necessary for the IMI Joint Undertaking to take out in order to meet its obligations;

(o) 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 18.

Article 7
Scientific Committee

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.

2. The Scientific Committee shall consist of no more than 15 members.

3. Such 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 Board shall establish the specific criteria and selection process for the composition of the Scientific Committee and appoint candidates subject to selection by the IMI Member States 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 Board and the Executive Office 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.

8. The Scientific Committee may, with the agreement of the chairperson, invite non-member persons to participate in its meetings for advice.

Article 8
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.

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 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 total contribution from the Community to the IMI Joint Undertaking covering running costs and Research Activities shall not exceed EUR 1 billion from the Seventh Framework Programme.

4. The running costs shall not exceed 4 % of the total budget of the IMI Joint Undertaking for the initial period ending on 31 December 2017. The running costs of the IMI Joint Undertaking shall be financed by its Members and shall be proportionate to the total contribution towards the Research Activities:

   (a) The Founding Members shall contribute in equal parts;

   (b) Any other Member shall contribute in proportion to its total contribution towards the Research Activities.

5. The Research Activities shall be jointly funded by its Members through:

   (a) voluntary contributions by the research based pharmaceutical companies that are full 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 3(2).

6. Contributions in kind shall be subject to an evaluation of their value and utility for carrying out the tasks of the IMI Joint Undertaking, and to acceptance by the Board.

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

8. Should any Member of the IMI Joint Undertaking, or any participating research based pharmaceutical company that is a full member of EFPIA, fail to meet its commitments concerning its agreed contributions, the Executive Director shall convene a meeting of the 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 full member of EFPIA, which appropriate measures should be taken.

9. 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.

Article 9
Financial commitments

1. Financial commitments of the IMI Joint Undertaking shall not exceed the amount of resources at its disposal.

2. Except in the case of winding up of the IMI Joint Undertaking, subject to Article 19, the excess revenue over expenditure shall not give rise to payments to the Members of the IMI Joint Undertaking.

Article 10
Financial year

The financial year shall correspond to the calendar year.

Article 11
Financial Regulation

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

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

3. The IMI Joint Undertaking's Financial Regulation shall be based on the principles of the Framework Financial Regulation[23]. It may depart from the Framework Financial

[23] OJ L 357, 31.12.2002 p. 72; corrigendum in OJ L 2, 7.12003, p. 39

Regulation where the specific operating needs of the IMI Joint Undertaking so require and subject to prior consultation with the Commission.

Article 12
Financial reporting

1. Every year, the Executive Director shall present to the Board a preliminary draft budget which shall include 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 financial 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 Board with all supplementary information needed for this purpose.

2. The Board shall forthwith communicate to the Executive Director its comments on the preliminary draft budget and in particular on the estimates of resources and expenditure for the following year.

3. Taking into account the comments received from the Board, the Executive Director shall prepare the draft budget for the following year. Before September 1 of each year, the Executive Director shall submit the annual budget to the Board for approval.

4. 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 Board for approval.

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.

Article 13
Annual 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.

2. An annual activity report shall describe the performed Research Activities and other activities during the previous year and the corresponding expenditure.

3. The expenditure shall be based on Members' financial contributions as well as contributions from participating research based pharmaceutical companies that are full members of EFPIA.

Article 14
Staff

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

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.

3. The staff expenditure shall be borne by the IMI Joint Undertaking.

Article 15
Liability and Insurance

1. The IMI Joint Undertaking shall be solely responsible for meeting its obligations.

2. The financial liability of the Members for the debts of the IMI Joint Undertaking is limited to their contribution already made for the running expenditure as set out in Article 8.

3. The IMI Joint Undertaking shall take out and maintain appropriate insurance.

Article 16
Conflict of Interests

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

Article 17
Research activities, Grant Agreements and Project Agreements

1. The IMI Joint Undertaking shall support research activities following competitive calls for 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, hereinafter referred to as Project Agreement, shall:

   (a) set up the appropriate arrangements for the implementation of the Grant Agreement;

   (b) govern the relationship between the participants in a project.

5. The Community contribution to the IMI Joint Undertaking shall be used for the implementation of the Research Activities. The following legal entities are eligible for such funding:

(a) micro, small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC[24];

(b) legal entities established as non-profit public bodies under national law;

(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.

Article 18
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 necessary for the operations of the IMI Joint Undertaking, according to the provisions of its financial regulation.

Article 19
Winding up

1. At the end of the period provided for in Article 1(3), or following a decision by the Council, 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 Board shall appoint one or more liquidators, who shall comply with the decisions of the 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.

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[24] O J L 124, 20.2003, p.36

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.

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 17 and service and supply contract referred to in Article 18, with duration longer than the duration of the IMI Joint Undertaking.

Article 20
Preparatory actions

The Founding Members shall be responsible for carrying out all activities relating to the establishment of the IMI Joint Undertaking until the bodies responsible for its operation have been set up.

Article 21
Amending the Statutes

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

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.

Article 22
Intellectual property 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 full 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 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
Applicable Law

In any matter not covered by these Statutes or by acts of Community law, the law of the state where the seat of the IMI Joint Undertaking is located shall apply.

LEGISLATIVE FINANCIAL STATEMENT

1. NAME OF THE PROPOSAL:

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

2. ABM / ABB FRAMEWORK

Policy Area(s) concerned and associated Activity/Activities:

Research and Technological Development: 7th Framework Programme, Specific Programme "Cooperation", Theme "Health"

3. BUDGET LINES

3.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B..A lines)) including headings:

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"

3.2. Duration of the action and of the financial impact:

The IMI Joint Undertaking is expected to be established by Council Decision before the end of 2007 for a period of up to 31 December 2017. Its financial impact on the EU budget will cease after 2013.

3.3. Budgetary characteristics :

Budget line	Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
08.02.01 10	Non-comp	Diff	YES	YES	YES	No 1 A
08.02 01 20	Non-comp	Non-diff	YES	YES	YES	No 1 A

4. SUMMARY OF RESOURCES

4.1. Financial Resources

All figures presented in this statement are indicative and presented in *constant* values.

4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Section no.		Year 2008	2009	2010	2011	2012	2013 and later	Total
Operational expenditure[25]									
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 expenditure within reference amount[26]									
Technical & administrative assistance (NDA)	8.2.4.	c	2.300	3.200	4.200	4.600	5.700	20.000	40.000
TOTAL REFERENCE AMOUNT									
Commitment Appropriations		a+c	125.000	80.000	100.000	160.000	300.000	235.000	1000.000
Payment Appropriations		b+c	125.000	80.000	100.000	160.000	300.000	235.000	1000.000
Administrative expenditure <u>not</u> included in reference amount[27]									
Human resources and associated expenditure (NDA)	8.2.5.	d	0.702	0.351	0.000	0.000	0.000	0.000	1.053
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	8.2.6.	e	0.335	0.109	0.166	0.166	0.000	0.166	0.942

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

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

27 The reference amount does not include the administrative expenditure from the Research budget that is not transferred to the IMI Joint Undertaking.

Total indicative financial cost of intervention

TOTAL CA including cost of Human Resources		a+c +d +e	126.037	80.460	100.166	160.166	300.000	235.166	1001.995
TOTAL PA including cost of Human Resources		b+c +d +e	126.037	80.460	100.166	160.166	300.000	235.166	1001.995

Co-financing details

The founding members of the IMI Joint Undertaking shall be:

- The European Community, represented by the Commission;

- The European Federation of Pharmaceutical Industries and Associations (hereinafter referred to as "EFPIA"), a non-profit association registered under Swiss law with its permanent office in Brussels, Belgium. EFPIA operates as a representative organisation of the Pharmaceutical Industry in Europe.

The running costs of the IMI Joint Undertaking shall be covered by its members (European Community and EFPIA). The European Community and EFPIA shall contribute on an equal level. The research activities of the IMI Joint Undertaking (operational costs) shall be covered by funding from the European Community and at least on an equal level by resources (in kind) from the research based pharmaceutical companies that are full members of EFPIA.

EUR million (to 3 decimal places)

Co-financing body		Year 2008	2009	2010	2011	2012	2013 and later	Total
EFPIA and the research based pharmaceutical companies that are full members of EFPIA	f	125.000	80.000	100.000	160.000	300.000	235.000	1000.000
TOTAL CA including co-financing	a+c+d +e+f	251.037	160.460	200.166	320.166	600.000	470.166	2001.995

4.1.2. Compatibility with Financial Programming

X Proposal is compatible with existing financial programming.

☐ Proposal will entail reprogramming of the relevant heading in the financial perspective.

☐ Proposal may require application of the provisions of the Interinstitutional Agreement[28] (i.e. flexibility instrument or revision of the financial perspective).

4.1.3. Financial impact on Revenue

X Proposal has no financial implications on revenue

☐ Proposal has financial impact – the effect on revenue is as follows:

EUR million (to one decimal place)

		Prior to action	Situation following action					
Budget line	Revenue	[Year n-1]	[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5][29]
	a) Revenue in absolute terms							
	b) Change in revenue	Δ						

4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.

Annual requirements	2008	2009	2010	2011	2012	2013 and later
Total number of human resources	17	28	34	34	36	174

5. CHARACTERISTICS AND OBJECTIVES

5.1. Need to be met in the short or long term

The needs are:

(a) To set up the IMI Joint Undertaking, as a new scheme of partnership between the Commission and industry for research funding;

(b) To organise the competitive calls for proposals, evaluation and selection of projects where industry will co-fund the selected collaborative research projects performed in A Member State or a country associated to the Seventh Framework Programme, together with academic, SMEs, and patients associations supported by the funds coming from the IMI Joint Undertaking;

[28] See points 19 and 24 of the Interinstitutional agreement.

[29] Additional columns should be added if necessary i.e. if the duration of the action exceeds 6 years

(c) To monitor and follow-up financial and scientific aspects (including the knowledge management) of projects having concluded a grant agreement with the IMI Joint Undertaking;

(d) To organise the calls for tender necessary to the operations of IMI Joint Undertaking,

(e) To set up and implement all procedures linked to the IMI Joint Undertaking, including financial auditing;

(f) To organise dissemination activities of the IMI Joint Undertaking;

(g) To organise the communication activities of the IMI Joint Undertaking;

(h) To organise any other activity linked to the IMI Joint Undertaking

5.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy

These issues are addressed in the impact assessment document attached to this proposal that is based on a socio-economic impact assessment performed by a panel of independent external experts, as well as on a "Keys to success" document provided by the industry.

5.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework

1) Objectives and expected results.

The Innovative Medicines Joint Technology Initiative (IMI JTI) aims to strengthen Europe's position in biopharmaceutical research. It will re-invigorate the European - pharmaceutical sector, make Europe more attractive to private R&D investment and, in the long term, provide European citizens with faster access to better medicines, improvement of their health, quality of life and well-being. IMI is expected to introduce a new dimension of research collaboration to the biopharmaceutical sector; between pharmaceutical companies, which normally compete, and with other key stakeholders, such as, small companies, academic scientists, clinicians, patients and regulators. IMI therefore responds to the major European policies, in particular the Lisbon and 3 % objectives. It will contribute towards establishing the European Research Area and it will also respond to calls for action recommended in report of the High Level Group on innovation and provision of medicines (G10 Medicines, 2002) and in report for "Creating an Innovative Europe" ("Aho report", 2006).

The IMI Joint Undertaking shall contribute to the implementation of the Seventh Framework Programme of the European Community for research, technology development and demonstration activities (2007-2013) and 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, and, in particular to:

- support 'pre-competitive pharmaceutical research and development' in Europe via a coordinated approach to overcome the identified research bottlenecks in the drug development process;

- support the implementation of the research priorities as set out by the Research Agenda of the IMI Joint Undertaking, notably by awarding grants following competitive calls for proposals;

- promote 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;

- conclude service and supply contracts necessary for the operations of the IMI Joint Undertaking;

- ensure the efficiency and durability of the Joint Technology Initiative on "Innovative Medicines".

2) Indicators are proposed in the impact assessment document attached to this proposal (see Audit).

Performance indicators shall be established in consultation with the relevant Commission services and in agreement with EFPIA (based on their position paper "Keys for Success") and shall take into account also advice from the independent expert group analysing the economy and societal effects of IMI JTI.

The performance indicators are distinguished into:

a) Indicators measuring the impact of IMI JU on EU competitiveness (e.g., amount of private investment R&D in the EU compared to the rest of the world).

b) Indicators measuring the impact of IMI on the Scientific Environment (number of validated biomarkers, new and amended regulatory guidelines, change in mean time to approval by therapeutic area).

These indicators will be measured and reported in every IMI JU annual activity report and the evolution and progress annually reported to the Council and Parliament by the Commission. In addition, they represent key points in assessing IMI JU performance in an interim evaluation in 2010 and final evaluation in 2017 by independent experts. In order to help assess IMI JU's additionality effects during its lifetime, it is foreseen that a series of "baseline studies" focusing on using this performance indicators in the pre-IMI-area (2005, 2006, 2007) will be performed.

5.4. Method of Implementation (indicative)

Show below the method(s)[30] chosen for the implementation of the action.

☐ ***Centralised Management***

- ☐ directly by the Commission
- X indirectly by delegation to:
  - ☐ executive Agencies
  - X bodies set up by the Communities as referred to in art. 185 of the Financial Regulation
  - ☐ national public-sector bodies/bodies with public-service mission

☐ ***Shared or decentralised management***

- ☐ with Member states
- ☐ with Third countries

☐ ***Joint management with international organisations (please specify)***

Relevant comments: Further details annexed.

6. MONITORING AND EVALUATION

6.1. Monitoring system

The Joint Undertaking will be monitored as provided in its Statutes.

6.2. Evaluation

6.2.1. Ex-ante evaluation

These issues are addressed in the impact assessment document attached to this proposal that is based on a socio-economic impact assessment performed by a panel of independent external experts, as well as on a "Keys to success" document provided by the industry. It provides most of the information required by an ex-ante evaluation on the establishment of the IMI Joint Undertaking.

6.2.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)

Not applicable.

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[30] If more than one method is indicated please provide additional details in the "Relevant comments" section of this point.

6.2.3. Terms and frequency of future evaluation

Described under Article 13 of the proposed Regulation.

7. ANTI-FRAUD MEASURES

Described under Article 14 of the proposed Regulation.

8. DETAILS OF RESOURCES

8.1. Objectives of the proposal in terms of their financial cost

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	Type of output	Av. cost	Year 2008		Year 2009		Year 2010		Year 2011		Year 2012		Year 2013 and later		TOTAL	
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost
OPERATIONAL OBJECTIVE No.1 [31] Implementing the Research Agenda of the IMI Joint Undertaking																
Action 1 Support for research projects																
- Output 1 (*)	Research Projects funded	10	13	122.700	7	76.800	10	95.800	16	155.400	29	294.300	21	215.000	96	960.000
TOTAL COST				122.700		76.800		95.800		155.400		294.300		215.000		960.000

(*) Compared to other Seventh Framework programme activities, projects to be supported under the IMI Joint Undertaking are expected to have a large scale, with an average total cost per project of € 20 million, out of which 50% (€ 10 million) is supported by the IMI JU (i.e. from EU contribution) and the other 50% (€ 10 million) by in kind contributions from research based pharmaceutical companies that are full members of EFPIA.

[31] As described under Section 5.3.

8.2. Administrative Expenditure

8.2.1. Number and type of human resources (indicative)

Types of post		Staff to be assigned to management of the action using existing and/or additional resources (**number of posts/FTEs**)					
		Year 2008	Year 2009	Year 2010	Year 2011	Year 2012	Year 2013 and later
Officials or temporary staff[32]	A*/AD	5	2	0	0	0	0
	B*, C*/AST	1	1	0	0	0	0
Staff financed[33] by art. XX 01 02		0	0	0	0	0	0
Other staff[34]	AD	6	14,5	22	22	23	110
	AST	3	5,5	7	7	8	36
	external	2	5	5	5	5	28
TOTAL		17	28	34	34	36	174

8.2.2. Description of tasks deriving from the action

The tasks of the IMI Joint Undertaking are described under Article 2 of the Statutes. The specific tasks of the Executive Director and the Executive office are described under Article 6 of the Statutes. In addition the preparatory actions for setting up the IMI Joint Undertaking are referred to in Article 17 of the Regulation

8.2.3. Sources of human resources (statutory)

- ☐ Posts currently allocated to the management of the programme to be replaced or extended
- ☐ Posts pre-allocated within the APS/PDB exercise for year n
- ☐ Posts to be requested in the next APS/PDB procedure
- X Posts to be redeployed using existing resources within the managing service (internal redeployment)
- X Posts required for year n although not foreseen in the APS/PDB exercise of the year in question

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32 Cost of which is NOT covered by the reference amount

33 Cost of which is NOT covered by the reference amount

34 Cost of which is included within the reference amount under 08.02 01 20 and the contribution from EFPIA

8.2.4. Other Administrative expenditure included in reference amount (08.02 01 20 "Support expenditures for running costs of the IMI Joint Undertaking")

EUR million (to 3 decimal places)

Budget line (number and heading)	Year 2008	Year 2009	Year 2010	Year 2011	Year 2012	Year 2013 and later	TOTAL
1 Technical and administrative assistance (including related staff costs)							
Executive agencies[35]							
Other technical and administrative assistance							
- *intra muros*							
- *extra muros*							
IMI Joint Undertaking (**)	2.300	3.200	4.200	4.600	5.700	20.000	40.000
Total Technical and administrative assistance	2.300	3.200	4.200	4.600	5.700	20.000	40.000

(**) The IMI Joint Undertaking will be established under Art. 171

Calculation– (for the duration of the IMI Joint Undertaking)

The indicative costs referred to in the table above only concerns the Community contribution to the running costs of the IMI Joint Undertaking. This contribution represents 50 % of the total running costs of the IMI Joint Undertaking..

Staff: average cost of € 117,000 per FTE per year for AD/AST, and € 51,000 per FTE per year for external. Community contribution amounts to € 16,7 million

Other running expenditure: Estimated Community contribution amounts to € 23.3 million, including: evaluation, monitoring of projects, communication activities, organisation of meetings, travel and subsistence, office running costs, IT, auditing, etc.

[35] Reference should be made to the specific legislative financial statement for the Executive Agency(ies) concerned.

8.2.5. Financial cost of human resources and associated costs not included in the reference amount

EUR million (to 3 decimal places)

Type of human resources	Year 2008	Year 2009	Year 2010	Year 2011	Year 2012	Year 2013 and later
Officials and temporary staff	0.702	0.351	0	0	0	0
Staff financed by Art XX 01 02 (auxiliary, END, contract staff, etc.) (specify budget line)						
Total cost of Human Resources and associated costs (NOT in reference amount)	**0.702**	**0.351**	**0**	**0**	**0**	**0**

Calculation– ***Officials and Temporary agents***

The human resources referred to in table 8.2.5 are calculated with an average cost of € 117,000 per FTE per year.

8.2.6. Other administrative expenditure not included in reference amount

EUR million (to 3 decimal places)

	Year 2008	Year 2009	Year 2010	Year 2011	Year 2012	Year 2013 and later	TOTAL
Missions	0.019	0.009					0.028
Meetings & Conferences	0.050						0.050
Committees[36]							
Studies & consultations	0.166		0.166	0.166		0.166	0.664
Information systems	0.100	0.100					0.200
2 Total Other Management Expenditure	0.335	0.109	0.166	0.166		0.166	0.942
3 Other expenditure of an administrative nature (specify including reference to budget line)							
Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)	0.335	0.109	0.166	0.166		0.166	0.942

[36] See details of calculation in the annex