

DEC. NR. 36  
10.10.08

**DECISION OF THE GOVERNING BOARD OF THE INNOVATIVE MEDICINES  
JOINT UNDERTAKING ON THE IMPLEMENTATION OF  
REGULATION (EC) No 1049/2001 OF THE EUROPEAN PARLIAMENT AND OF  
THE COUNCIL REGARDING PUBLIC ACCESS TO DOCUMENTS**

THE GOVERNING BOARD OF THE INNOVATIVE MEDICINES JOINT  
UNDERTAKING,

Having regard to Council Regulation (EC) No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of a Joint Technology Initiative in Innovative Medicines<sup>1</sup>, and in particular Article 14(2) thereof and Article 5(2) (r) of the Statutes annexed thereto,

Whereas:

(1) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents<sup>2</sup> lays down the general principles and limits governing the right of access to European Parliament, Council and Commission documents.

(2) In accordance with Article 14 of Council Regulation (EC) No 74/2008, Regulation (EC) No 1049/2001 shall apply to documents held by the Joint Undertaking.

(3) In principle, the widest possible access to documents should be ensured, subject to the principles, conditions and limits defined in Regulation (EC) No 1049/2001.

HAS ADOPTED THIS DECISION:

*Article 1 – Purpose*

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<sup>1</sup> OJ L 30, 04.02.2008, p. 38

<sup>2</sup> OJ L 145, 31.05.2001, p. 43.

The scope of this Decision is to lay down the practical arrangements for implementing Regulation (EC) No 1049/2001 as regards the Joint Undertaking's documents.

*Article 2 – Scope and beneficiaries*

1. Citizens of the European Union and natural or legal persons residing or having their registered office in an EU Member State shall exercise their right of access to the Joint Undertaking's documents pursuant to Article 2(1) of Regulation 1049/2001.

2. Pursuant to Article 2(2) of Regulation 1049/2001, citizens of third countries not residing in an EU Member State and legal persons not having their registered office in one of the EU Member States shall enjoy the right of access to the Joint Undertaking's documents on the same terms as the beneficiaries referred to in Article 2(1) of Regulation 1049/2001.

*Article 3 – Definitions*

For the purpose of this Decision:

(a) 'Document' shall mean any content whatever its medium (written on paper or stored in electronic form or as a sound, visual or audiovisual recording) concerning a matter relating to the activities and decisions falling within the Joint Undertaking's sphere of responsibility.

(b) 'Third Party' shall mean any natural or legal person, or any entity outside the Joint Undertaking, including its Members, Community or non-Community institutions and bodies and third countries.

*Article 4- Access applications*

1. Applications for access to a document shall be sent to the Joint Undertaking via the Joint Undertaking's website, by electronic mail, by regular mail or by fax, preferably in English and in a sufficiently precise manner to enable the Joint Undertaking to identify the document. The relevant contact details are listed in the Annex to this Decision and shall be regularly updated.

2. The Joint Undertaking shall respond to initial and confirmatory applications within fifteen working days from the date of registration of the application, by regular mail, by electronic mail or by fax.

3. In the case of complex or bulky applications, the deadline may be extended by fifteen working days. Reasons must be given for any extension of the deadline and any such extension must be notified to the applicant prior to the expiry of the original deadline.

4. If an application is imprecise, as defined in Article 6(2) of Regulation 1049/2001, or in a language other than English, the Joint Undertaking shall invite the applicant to provide additional information to clarify the application. The deadline for the Joint Undertaking to respond to the application shall be fifteen working days from receiving the information necessary to identify the document in question.

5. Any decision to deny access to a document or part of a document shall state the reason for the refusal based on one of the exceptions listed in Article 4 of Regulation 1049/2001. The applicant shall be informed of the remedies available to him/her.

6. Pursuant to Article 17(1) of Regulation 1049/2001, a report shall be annexed to the Joint Undertaking's Annual Activity Report including the number of cases in which the Joint Undertaking refused to grant access to documents, the reasons for such refusals and the number of sensitive documents not recorded in the register.

#### *Article 5- Processing of initial applications*

1. Where the document requested is directly accessible as defined in Article 12 of Regulation 1049/2001 and in Article 11 of this Decision, the applicant shall be notified as such together with details of how to retrieve the document in question.

2. Applications relating to documents which are not directly accessible shall be acknowledged by the Joint Undertaking pending an answer unless this answer can be sent by return post.

3. The acknowledgement of receipt and the answer shall be sent to the applicant in writing, where appropriate, by electronic means.

4. The Joint Undertaking shall inform the applicant of its decision with respect to the initial application.

5. In the event of a total or partial refusal, the applicant shall be informed of his/her right to submit, within fifteen working days from receipt of the answer, a confirmatory application to the Executive Director asking him/her to reconsider this refusal.

6. Failure of the Joint Undertaking to reply within the prescribed time limit shall entitle the applicant to make a confirmatory application.

*Article 6- Processing of confirmatory applications*

1. The Executive Director of the Joint Undertaking shall take decisions regarding confirmatory applications.

2. The decision shall be notified to the applicant in writing, where appropriate, by electronic means, and shall inform him/her of his/her right to bring an action before the Court of First Instance or, if applicable, to lodge a complaint with the European Ombudsman.

3. Failure of the Joint Undertaking to reply within the prescribed time limit shall be considered as a negative reply.

*Article 7- Third-party documents*

1. Where the Joint Undertaking receives an application for access to a document which it holds but which originates from a third party, the Joint Undertaking shall check whether one of the exceptions provided for under Article 4 of Regulation 1041/2001 applies.

2. If, after that examination, the Joint Undertaking considers that access to the document must be refused under one of the exceptions provided for by Article 4 of Regulation 1049/2001, the negative answer shall be sent to the applicant with copy to the third-party author.

3. The Joint Undertaking shall grant the application without consulting the third-party author where:

- a) the document requested has already been disclosed either by its author or under Regulation 1049/2001 or similar provisions;
- b) it is clear that the disclosure, or partial disclosure, of its contents would not affect one of the interests referred to in Article 4 of Regulation 1049/2001;
- c) the document is classified as directly accessible to public by a Governing Board decision<sup>3</sup>.

4. In all other cases, the third-party author shall be consulted. In particular, if an application for access concerns a document originating from an EU Member State, the Commission, or other Member, the Joint Undertaking shall consult the originating authority where the EU Member State, the Commission, or other Member has requested the Joint Undertaking not to disclose the document without its prior agreement in accordance with Article 4(5) of Regulation 1049/2001.

5. The third party consulted shall be given a deadline for reply which shall allow the Joint Undertaking to respect its own deadline to reply to the applicant. In the absence of an answer within the prescribed period, or in those cases where the third party is untraceable or unidentifiable, the Joint Undertaking shall reach a decision in accordance with the criteria set out in Article 4 of Regulation 1049/2001, taking into account the legitimate interests of the third party on the basis of the information at its disposal.

6. If the Joint Undertaking intends to give access to a document against the explicit opinion of the author, it shall inform the author of its intention to disclose the document after a ten-working day period and shall draw his/her attention to the remedies available to him/her to oppose disclosure.

#### *Article 8 – Classification of documents*

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<sup>3</sup> See the Guidance on the Disclosure of Types of Human and Veterinary Medicines Information held by the Human and Veterinary Regulatory Authorities following the Memorandum of understanding between the ABPI and the MHRA.

1. The Joint Undertaking's documents shall be classified in accordance with the classification laid down in Commission Decision (EC, ECSC, Euratom) No 2001/844 of 29 November 2001 amending its internal Rules of Procedure<sup>4</sup>.
2. The classification of a document of the Joint Undertaking shall be decided by the Executive Director. When the classification raises questions of principle and/or when the document is related to the work of one of the Joint Undertaking's bodies, the Executive Director may consult the relevant Chairperson before taking his/her decision.
3. Applications for access to classified documents shall be handled by the Executive Director, where appropriate in consultation with the relevant Chairperson as referred in paragraph 2.
4. If access to a classified document is to be given, it shall be first declassified by a decision of the Executive Director.

*Article 9- Exercise of the right of access*

1. Documents shall be sent by regular mail, fax or, if possible, by electronic mail. If documents are voluminous or difficult to handle, the applicant may be invited to consult the documents at the Joint Undertaking's premises. This consultation shall be free of charge.
2. If the document has been published, the answer shall consist of the publication references or, for documents available on the Joint Undertaking's website or other websites, the appropriate Uniform Resource Locator (URL).
3. If the volume of the documents requested exceeds twenty pages, the applicant may be charged a fee of 0,10 EUR per page for copies plus carriage costs. The charges for other media shall be decided on a case by case basis but shall not exceed a reasonable amount.

*Article 10- Measures facilitating access to documents*

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<sup>4</sup> OJ L 317, 3.12.2001, p. 1.

1. In order to make the right of access provided for in Regulation 1049/2001 effective, the Joint Undertaking shall provide access to a register of documents. The register shall be accessible in electronic form.
2. The register shall contain the title of the document (in the languages in which it is available), its serial number, the subject matter and/or a short description of the contents, an indication of the author, the date of its creation or adoption and the date of entry in the register.
3. For documents which are directly accessible, the register shall include a hyperlink to the document in question.
4. A help page shall be provided to assist the public in finding specific documents.
5. For documents which are not directly accessible, the register shall provide details of how to request access.

*Article 11- Documents directly accessible to the public*

1. The following documents shall be made directly accessible by electronic means:
  - (a) all adopted EU legislation related to the Joint Undertaking's objectives;
  - (b) a publishable version of the of the Annual Implementation Plan and of the Annual Activity Report once approved by the Governing Board;
  - (c) the Annual Budget Plan and amending budgets as finally adopted;
  - (d) the Annual Implementation Plan as finally adopted;
  - (e) all press releases or other publications made by the Joint Undertaking.
  - f) the decisions of the Governing board adopted
2. As far as possible the following documents shall be made directly accessible by electronic means:
  - (a) documents originating from third parties which have already been disclosed by their author or with his/her consent;
  - (b) documents already disclosed following a previous application.

3. The Executive Director may decide to expand the list of documents in paragraph 2 as appropriate.

*Article 12-Internal Organisation*

The Executive Director shall ensure coordination and uniform implementation of these rules by the Joint Undertaking staff. To this end, he/she shall provide all the necessary advice and guidelines.

*Article 13 - Right of Access to Personal Data*

This Decision shall be without prejudice to the right of individuals to have access to personal data concerning them as stipulated in relevant Community legislation, such as Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000.

*Article 14 - Reproduction of Documents*

This Decision shall be without prejudice to any existing rules on copyright which may limit a third party's right to reproduce or exploit released documents.

*Article 15 - Amendment*

This Decision may be amended by a subsequent decision of the Governing Board.

*Article 16- Entry into force*

This Decision shall enter into force on the date of its signature and shall be published on the website of the Joint Undertaking.

Done at Brussels, 10 October 2008

For the Governing Board of the Joint Undertaking

Chairperson of the Governing Board

*Jonathan Knowles*



## ANNEX

Addresses for submission of applications for access to documents held by the Innovative Medicines Initiative 2 Joint Undertaking (*data updated subsequent to adoption of this decision*)

**1. By post:**

Innovative Medicines Initiative 2 Joint Undertaking  
Access to Documents  
IMI2 JU, TO 56  
B-1049 Brussels, Belgium

**2. By electronic mail:**

[access.to.documents@imi.europa.eu](mailto:access.to.documents@imi.europa.eu)

**3. Via the Joint Undertaking's website:**

<https://www.imi.europa.eu/reference-documents>

**4. By fax:**

+32(0)2 221 81 74