



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 February 2018
EMA/MB/102052/2018 Adopted
Management Board

Minutes of the Extraordinary Management Board meeting for the building approval process of EMA premises in Amsterdam

Held in Lisbon on 28 February 2018

The chair opened the meeting expressing gratitude to the Portuguese National Authority of Medicines and Health Products INFARMED for their hospitality and support in organising the extraordinary meeting at the margins of the meeting of the Heads of Medicines Agencies in Lisbon. She thanked the members for their attendance on short notice and for their willingness to accept shortened timelines for the provision of documents necessary to observe the strict timeframe of the building approval process. The chair welcomed Alexandru Velicu, new member for Romania. A number of proxies had been received from members who could not attend the meeting and would be read out should a vote be taken. The meeting took place as an extraordinary meeting according to Art. 4 of the Rules of Procedure of the Management Board, and was organised to allow the board to examine additional information provided by the Dutch government following a request made by the board at the previous extraordinary meeting on 6 February 2018. The meeting was held in camera and was attended only by members or their alternates, the observers from EEA countries and a limited number of EMA staff, as well as by two representatives of the Dutch government invited to attend points 4. and 5. of the Agenda to provide clarifications.

Following the meeting of 6 February, the chair had written to Mr Alexander Italianer, Secretary-General of the European Commission seeking clarifications on the interpretation of the July bid by the Dutch government on which the decision on the new location of the Agency was taken on 20 November 2017, as well as to Dr Bruno Bruins, Dutch Minister of Health, Welfare and Sports to reconsider the proposal to bring it in line with the financial offer included in the bid presented in July. Answers had been received to both letters and circulated to the board with the meeting documents.

The chair took the occasion of this extraordinary meeting to remind old and new members of the board's primary duty and of its members as a whole to assure the good governance of the Agency.

1. Draft agenda for 28 February 2018 meeting

[EMA/MB/102050/2018] The agenda was adopted with no amendments.



2. Declaration of competing interest related to current agenda

The Secretariat informed members of the Management Board that it had reviewed members' declared interests in accordance with the Board's policy on the handling of competing interests. The Secretariat identified no items regarding the agenda that would cause any members to refrain from decision-making, and/or topic-coordinator type of activity, as relevant.

Members were asked to declare any specific interests that could not be drawn from their current declaration of interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interest were declared.

3. Minutes of the Extraordinary Management Board meeting for the building approval process of EMA premises in Amsterdam held on 6 February 2018

[EMA/MB/84505/2018] The Management Board adopted the minutes of the extraordinary meeting of the Management Board held on 6 February 2018. The minutes will be published together with the minutes of the extraordinary meeting of 28 February 2018 once these are adopted.

4. Follow-up to 6 February 2018 Extraordinary Management Board meeting

[1304828-173926-GMT; Ref. Ares(2018)997396 - 21/02/2018] The board was informed by the Deputy Executive Director of events that took place after the extraordinary meeting of the Management Board on 6 February 2018. The Agency and the representatives of the government of the Netherlands had held discussions at meetings on 9 and 16 February 2018. As an outcome of the meetings, and following the letter sent by the chair of the Management Board to the Dutch Minister of Health, Welfare and Sport, the Dutch government agreed to submit a revised offer which should address the concerns raised by the board and would be in line with the bid submitted in July 2017. It was also agreed to further review which EMA requirements should be considered additional requirements of EMA. In addition to the high level EMA requirements set out to the board in March 2017 and in Annex 1 of the Council procedure leading up to a decision on the relocation of the European Medicines Agency in the context of the United Kingdom's withdrawal from the Union, several requirements had been provided to the Dutch authorities over the last months for finalising the Programme of Requirements referred to in the Memorandum of Understanding agreed between the EMA and the Dutch government in December 2017. At the extraordinary meeting of 6 February 2018 following an initial review a first set of requirements which should be considered as additional requirements had been presented to the board. A more thorough review of all requirements submitted after 20 November 2017 has identified the requirements which may be considered additional and for which the Agency would accept to be financially responsible. The final programme of requirements will be annexed to the lease agreement for the permanent building to be signed by the Agency and the Dutch government. Responses had been received to the letters sent by the Management Board chair. The Secretariat General informed that is not in a position to reply to the request for clarification on the Dutch bid to host the European Medicines Agency. However, it reiterated its assessment of the price-per-square-metre net floor area of EUR 300 to EUR 320 in combination with a 20-year lease period notwithstanding any additional requirements and fitting out of the building, which is to be specified by the EMA. The response

received from the Dutch Minister of Health, Welfare and Sport on 23 February formed the revised offer for discussion at the present meeting.

5. Notification of the European Medicines Agency's intention to move to a new building in accordance with Article 88 of the Agency's Financial Regulation

[EMA/MB/120553/2018; EMA/749315/2017 – MB Version 3 and Annexes] The Management Board endorsed the notification to the Budgetary Authority of the European Medicines Agency's intention to move to a new building. The board was reminded of its role in the building approval process and of the elements that made up the bid by the Dutch government to host the European Medicines Agency in Amsterdam. Members were invited to compare the revised offer of 23 February with the financial offer presented on 19 January and with the offer contained in the Dutch bid submitted on 28 July 2017. In particular, the annual rent per m² LFA (lettable floor area) to be charged to the Agency amounts now to € 280 and includes the car and bike parking spaces and fit-out of the building, while the annual maintenance costs amount now to € 40 compared to € 55 in the previous offer, bringing the annual rent per m² LFA including parking, fit-out and maintenance to € 320, therefore in line with the costs stated in the July bid. A comparison of costs including maintenance and operating costs with the current London building in Churchill Place shows a saving of 37% in future projected cost for 2020. It should however be taken into account that in the Netherlands a yearly indexation is common practice (as governed by General Terms and Conditions for lease agreements of office premises), and it has been proposed at a fixed rate of 2% in the revised offer. The additional requirements for which the Agency would accept to remain financially responsible concern network and telephony equipment and services, audio-visio enhancements, fit-out enhancements, additional furniture requirements, security systems and catering equipment taking into account conference facilities, for a total investment contribution of € 15 million. The Dutch offer includes an incentive of € 18 million which can be used by the Agency to cover the first instalment on the rent for the permanent building, to cover additional cost for EMA specific building requirements or to obtain an overall reduction of the annual rental costs for the duration of the lease agreement. The Agency has chosen to use up to € 15 million to cover its additional requirements and to use the remaining € 3 million for an overall reduction of the annual rental costs, i.e. on average € 150,000 per year for 20 years. The move of the Agency from the UK to the permanent premises in Amsterdam will be pre-financed from the Agency's budget while the move from the temporary to the permanent premises will be paid for by the Dutch government. The Agency will be the sole occupant of the building and will lease it for a 20-year duration from the State of the Netherlands, represented by the Dutch Central Government Real Estate Agency (CGREA). A diplomatic break clause stipulating the possibility for early termination in case of further relocation of the Agency will be included in the lease. Subject to the notification to the Budgetary Authority in time for the March session of the European Parliament, start of construction will begin in June 2018 and EMA will start moving into the permanent premises by 15 November 2019.

Members of the board welcomed the new proposal, which they found to be in line with expectations and therefore acceptable. The representatives of the European Commission agreed, and thanked the Dutch government and the Agency for all the work done. They referred to issues of detail raised by DG BUDG. While the proposal can be accepted, the board needs to be aware of some of the choices involved ahead of the transmission to the Budgetary Authority: the figure for the expenditure of € 15 million for additional requirements of the Agency should be seen as a ceiling and all remaining sums be allocated for the payment of rent together with the earmarked € 3 million; transparency of pricing should be ensured; according to the principle of net present value, a present amount of € 3 million is

worth more than 20 annual tranches of € 150.000; the indexation of the rent is common practice but the fixed increase appears unusual because common practices are usually related to actual inflation. The Executive Director agreed with the observations on the expenditure for additional requirements and on transparency of prices, which have been and will be handled in conformity to the Financial Regulation and in close consultation with DG BUDGET. Concerning the scheduling of rental payments and the indexation, these have to be seen as resulting from a complex negotiation leading to the current offer of a package, and cannot be called into question as single points. The board members acknowledged the clarification of the revised offer provided by the Executive Director and the secretariat. These matters will be considered by the Budgetary Authority during the building approval process. A member raised the topic of the current legislative procedure on the seat of the Agency at the European Parliament, together with doubts on preparedness of the building that had led to a delegation of the ENVI committee to visit Amsterdam on a fact finding mission. He questioned whether in this light it was appropriate to endorse the notification before a positive vote on the seat of the Agency had taken place at the European Parliament. The Executive Director asked members to make a distinction between the role of the European Parliament in legislative and in budgetary matters, and invited the board not to postpone the notification further, so as to allow the European Parliament Budget Committee to take a decision on 22 March, after the vote on the seat of the Agency on 14 March in the framework of legislative amendments to Regulation (EC) no. 726/2004. Ahead of leaving the room for deliberations by the board the representatives of the Dutch government confirmed that on the occasion of the visit of the ENVI committee to the building site and the Spark building in Amsterdam MEPs had been provided with information on how the project is being handled and with assurance that both the temporary and the permanent buildings will be delivered in time. In particular, the permanent building will be delivered on 15 November 2019 as scheduled. On request by the same member warning from endorsing the notification ahead of the vote on the seat of the Agency in the European Parliament the proposal was put to a vote.

24 votes in favour out of 36 are required to adopt a decision. The proxies were announced (details in the List of participants). The vote took place openly, in full view of all present. The outcome of the vote was as follows:

Total no. votes	Votes cast	Votes in favour	Votes against	Abstained	Not present
36	35	32	2	1	1

The full details of votes by delegation can be found in Annex 1.

The notification of the European Medicines Agency's intention to move to a new building will be sent to the Budgetary Authority which will be made aware of the comments by the European Commission. The representatives of the Dutch government were informed of the conclusions by the board.

List of participants at the Extraordinary Management Board meeting, held in Lisbon, 28 February 2018

Chair: Christa Wirthumer-Hoche

	Participants
Belgium	Xavier De Cuyper (<i>member</i>)
Bulgaria	Bogdan Kirilov (<i>alternate</i>)
Croatia	Siniša Tomić (<i>alternate</i>)
Czech Republic	<i>Apology received from Jiří Bureš</i> <i>Proxy to Hungary</i>
Denmark	Thomas Senderovitz (<i>member</i>)
Germany	Karl Broich (<i>member</i>)
Estonia	Kristin Raudsepp (<i>member</i>)
Ireland	Lorraine Nolan (<i>member</i>)
Greece	Aikaterini Antoniou (<i>member</i>)
Spain	Belén Crespo Sánchez- Eznarriaga (<i>member</i>)
France	Jean-Pierre Orand (<i>alternate</i>)
Italy	Nando Minnella (<i>alternate</i>)
Cyprus	Loizos Panayi (<i>member</i>)
Latvia	Svens Henkuzens (<i>member</i>)
Lithuania	Gintautas Barcys (<i>member</i>)
Luxembourg	<i>Apology received from Laurent Mertz (member)</i> <i>Proxy to the Netherlands</i>
Hungary	Csilla Pozgay (<i>member</i>)
Malta	John-Joseph Borg (<i>member</i>)
Netherlands	Hugo Hurts (<i>member</i>)
Austria	<i>Apology received from Thomas Reichhart</i> <i>(alternate)</i> <i>Proxy to Germany</i>
Poland	Marcin Kolakowski (<i>alternate</i>)
Portugal	Rui Santos Ivo (<i>member</i>)
Romania	Alexandru Velicu (<i>member</i>)
Slovakia	<i>Apology received from Zuzana Baťová (member)</i> <i>Proxy to Hungary</i>
Slovenia	Andreja Čufar (<i>member</i>)
Finland	Esa Heinonen (<i>alternate</i>)
Sweden	Catarina Andersson Forsman (<i>member</i>)
United Kingdom	Ian Hudson (<i>member</i>)
European Parliament	Björn Lemmer <i>Apology received from Tonio Borg</i> <i>Proxy to Björn Lemmer</i>
European Commission	Carlo Pettinelli (<i>DG GROW</i>) Andrezj Rys (<i>DG SANTE - alternate</i>)
Representatives of patients' organisations	<i>One member awaiting nomination</i> <i>Apology received from Yann le Cam</i> <i>Proxy to Denmark</i>

	Participants
Representative of doctors' organisations	<i>Apology received from Wolf Dieter Ludwig Proxy to Germany</i>
Representative of veterinarians' organisations	<i>Apology received from Nancy de Briyne Proxy to Spain</i>
Observers	Runa Hauksdottir Hvannberg (Iceland) <i>Apology received from Brigitte Batliner (Liechtenstein)</i> <i>Apology received from Audun Hågå (Norway)</i>

European Medicines Agency	Guido Rasi Noël Wathion Stefano Marino Nerimantas Steikūnas Maria Alves Rebecca Harding Silvia Fabiani Sophia Albuquerque
---------------------------	--

Dutch delegation present:	Maurice Galla (<i>observer</i>) (<i>partial attendance</i>) Aginus A. W Kalis (<i>observer</i>) (<i>partial attendance</i>)
---------------------------	--

Annex 1 - Vote on agenda item B.5 – Notification of the European Medicines Agency’s intention to move to a new building in accordance with Article 88 of the Agency’s Financial Regulation

In favour	Against	Abstained	Not present
32	Italy Romania	United Kingdom	1