



8 September 2017  
EMA/399439/2017  
European Medicines Agency

## EMA technical comments on the technical requirements with respect to the candidate host Member States' offers to relocate the European Medicines Agency

Applied methodology

### 1. Introduction

Reference is made to the letter dated 22 August 2017 from the EC to EMA inviting EMA to provide technical comments for each of the 19 submitted offers.

These technical comments relate, as requested, to the following elements:

1. The proposed building(s) with indicated lay-out and facilities: on the basis of criterion 1 in point 2 of the fact sheet on EMA, attached as Annex 1 to the note on the procedure endorsed by the European Council<sup>1</sup>.
2. The relocation plan: on the basis of specific issue a) and criterion 5 of the note.

### 2. Preliminary remarks

In order to explain the methodology applied by EMA for providing technical comments, the following preliminary remarks, including assumptions, should be taken into account:

- Since the technical comments on the technical requirements for each of the 19 submitted offers are provided, as requested by the EC in their letter dated 22 August 2017, solely on the basis of the information provided in the offers (either publicly available information or confidential documents/information for which access to EMA was granted<sup>2</sup>), it is assumed that the statements made by the Member States (MSs) in their offers is correct and that implementation of the technical requirements as per the EMA fact sheet is feasible and will be undertaken by the MSs in full compliance with the EMA fact sheet and by the stated deadlines, hence ensuring continuity of EMA operation.

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<sup>1</sup> Procedure leading up to a decision on the relocation of the European Medicines Agency and the European Banking Authority in the context of the United Kingdom's withdrawal from the Union (ref.: XT 21045/17, dated 22 June 2017), endorsed by the Heads of State or Government on 22 June 2017.

<sup>2</sup> Access to EMA was granted to confidential documents/information provided by the Member States for the following cities: Amsterdam, Barcelona, Bratislava, Bucharest, Copenhagen, Dublin, Porto, Vienna.



- Since in a number of bids several buildings are proposed, it is assumed that the priority given by the MSs regarding the proposed building(s) is correct. Where no priority was given, EMA provided technical comments on all proposed buildings. Where a priority was given, technical comments were only made on the prioritised proposed building(s).
- Likewise, if a MS indicated that the proposed building was not ready on time and fully operational by the end of March 2019, and a temporary building was proposed, EMA provided technical comments on the basis of the combined proposed solution, however without performing a technical assessment of the temporary building in the absence of sufficient information for such temporary building.

### 3. Explanation of the methodology used for EMA’s technical comments

#### 3.1. Classification of EMA’s technical comments

EMA’s technical comments have been classified as follows:

- MS offer meets EMA requirements and ensures that EMA is operational on time.
- MS offer meets EMA requirements but raises concerns that EMA is operational on time.
- MS offer only partially meets EMA requirements and, therefore, raises major concerns as regards EMA business continuity.
- MS offer does not meet EMA requirements and, therefore, does not ensure EMA business continuity.

To further facilitate the review of EMA’s technical comments a colour code has been introduced for the aforementioned classification.

#### 3.2. Parameters used

The following parameters have been used to undertake the technical assessment:

Lay-out of the proposed premises	
Parameter	Methodology used
<b>Timely availability of the new EMA premises</b>	
<ul style="list-style-type: none"><li>• Minimum 27,000m<sup>2</sup> of offices space</li><li>• Separating the space into:<ul style="list-style-type: none"><li>– 250m<sup>2</sup> reception area</li><li>– Disability access for the reception area</li><li>– Enclosed lounge 500m<sup>2</sup> (for industry) and lounge for 50 persons (for delegates)</li></ul></li><li>• Auditorium for some 300 persons</li></ul>	<ul style="list-style-type: none"><li>• Statement in the offer that minimum 27,000m<sup>2</sup> of offices space are available</li><li>• Each aspect to be specifically referenced in the offer</li></ul>

<ul style="list-style-type: none"> <li>Offices ready in time to take up function at withdrawal date</li> </ul>	<ul style="list-style-type: none"> <li>Availability date specified and no later than 31 March 2019</li> <li>Offices meet the requirements as per the EMA fact sheet</li> </ul>
<ul style="list-style-type: none"> <li>Meeting facilities ready in time to take up function at withdrawal time</li> </ul>	<ul style="list-style-type: none"> <li>Availability date specified and no later than 31 March 2019</li> <li>Meeting facilities meet the requirements as per the EMA fact sheet</li> </ul>
<ul style="list-style-type: none"> <li>Archiving facilities ready on time</li> </ul>	<ul style="list-style-type: none"> <li>Availability date specified and no later than 31 March 2019</li> <li>Archiving facilities meet the requirements as per the EMA fact sheet</li> </ul>
<ul style="list-style-type: none"> <li>Other building facilities (IT build and IT store rooms, technical rooms, main and secondary equipment rooms) ready on time</li> </ul>	<ul style="list-style-type: none"> <li>Availability date specified and no later than 31 March 2019</li> <li>Other building facilities meet the requirements as per the EMA fact sheet</li> </ul>
<b>Parameter</b>	<b>Methodology used</b>
<b>New premises not available on time</b>	
<ul style="list-style-type: none"> <li>Premises specified as referred to above not available on time</li> </ul>	<ul style="list-style-type: none"> <li>Availability date specified</li> <li>Temporary solution to ensure business continuity specified</li> <li>Plan to specify how to go from the temporary to the final solution is available</li> </ul>

<b>Proposed facilities of the proposed premises</b>	
<b>Parameter</b>	<b>Methodology used</b>
<ul style="list-style-type: none"> <li>IT (Centralised Uninterruptible Power Supply, Wi-Fi, telecommunications network, main and back-up data centre, IT security) ready on time</li> </ul>	<ul style="list-style-type: none"> <li>Availability date specified and no later than 31 March 2019</li> <li>Each aspect to be specifically referenced in the offer and requirements are met as per the EMA fact sheet</li> </ul>
<ul style="list-style-type: none"> <li>Physical security (access control system, adequate security structure in the vicinity, CCTV)</li> </ul>	<ul style="list-style-type: none"> <li>Availability date specified and no later than 31 March 2019</li> <li>Each aspect to be specifically referenced in the offer and requirements are met as per the</li> </ul>

ready on time	EMA fact sheet
<ul style="list-style-type: none"> <li>Conference facilities (AV conference facilities, broadcasting and recording equipment, voting system per seat) ready on time</li> </ul>	<ul style="list-style-type: none"> <li>Availability date specified and no later than 31 March 2019</li> <li>Each aspect to be specifically referenced in the offer and requirements are met as per the EMA fact sheet</li> </ul>

<b>Relocation plan</b>	
<b>Parameter</b>	<b>Methodology used</b>
<ul style="list-style-type: none"> <li>Proposed timeframe</li> </ul>	<ul style="list-style-type: none"> <li>Information provided in the offer as regards how and when the relocation should take place, with timelines and milestones</li> </ul>
<ul style="list-style-type: none"> <li>Modalities for planning tasks</li> </ul>	<ul style="list-style-type: none"> <li>Information provided in the offer, in particular as regards the governance structure ( e.g. availability of steering committee, task force) and whether the offer specifies procurement support provided by the MS to EMA</li> </ul>
<ul style="list-style-type: none"> <li>Any necessary adaptation works to the premises</li> </ul>	<ul style="list-style-type: none"> <li>Information provided in the offer with respect to any adaptation needed to either an existing building or an ongoing construction, including the feasibility of such adaptation works</li> </ul>
<ul style="list-style-type: none"> <li>Physical removal</li> </ul>	<ul style="list-style-type: none"> <li>Information detailing how the MS would support EMA in relocating on time, hereby ensuring continuity of operation</li> </ul>