

15 September 2017 EMA/606600/2017 European Medicines Agency

Candidate host Member States' offers to relocate the European Medicines Agency - EMA comments on other criteria essential to ensure that EMA remains operational to guarantee business continuity

Applied methodology

1. Introduction

Reference is made to the document "EMA technical comments on the technical requirements with respect to the candidate host Member States' offers to relocate the European Medicines Agency – Applied methodology" (EMA/399439/2017), which describes the methodology applied by EMA to provide technical comments for each of the 19 submitted offers as regards (1) the proposed building(s) with indicated lay-out and facilities, and (2) the relocation plan.

The current document outlines the methodology used by EMA to provide comments on the other criteria listed in the note on the procedure endorsed by the European Council¹. Such comments are made in view of the critical nature of the services provided by EMA and the need, therefore, to ensure continued functionality at the existing high level, as explicitly recognised in the aforementioned note (in particular criterion 5) Business continuity).

2. Preliminary remarks

In order to explain the methodology applied by EMA for providing comments on the other criteria essential to ensure that EMA remains operational to guarantee business continuity, the following preliminary remarks, including assumptions, should be taken into account:

• For these comments, EMA has taken into account the information provided in the offers submitted by the Member States (MSs), as well as other publicly available information. EMA did not have access to any confidential documents/information provided by the MSs on these criteria as part of their offers. With respect to statements made by the MSs in such offers, it is assumed that these statements are correct.

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¹ 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.

- In case publicly available information other than information provided in the offers has been used by EMA, the data source is specified.
- A small number of parameters for certain criteria undergo seasonal variations (such as for instance flight connections where the summer business period schedule and the autumn business period schedule differ). In those situations, EMA has clearly specified which approach is taken to perform the assessment.

3. Explanation of the methodology used for EMA's comments

3.1. Classification of EMA's comments

EMA's 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 comments a colour code has been introduced for the aforementioned classification.

3.2. Parameters used

The following parameters have been used to undertake the assessment:

Criterion 2: Accessibility of the location Flight connections within the EEA		
Choice of cities	• Flights between the other MSs (capital city and/or other city (as regards the latter, the city of the National Competent Authority (NCA) if such city is not the capital city) and the candidate host city of the candidate host MS	NCAs' websites
Choice of airport	• The document "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" states under criterion 2) The accessibility of the	Classification list of IATA (International Air Transport Association)

Criterion 2: Accessibility of the location		
	 location: "flight connections from the capitals of all EU Member States to the airports close to the location". Since no definition of "close to the location" is given it is important to provide for a consistent approach for all MSs' offers, keeping in mind the need to ensure that experts from all MSs across the EEA coming to EMA on a daily basis can travel as efficiently as possible in order not to undermine business continuity To address this, airports have been identified from the classification list of IATA for both the other MSs (capital city and/or other city as explained above) and the candidate host city of the candidate host MS. The statement "close to the location" has been interpreted as all airports identified in the IATA classification list linked to the candidate host city 	
Choice of airline	All airlines have been considered, including low-cost airlines	• N/A
Days of the week with direct flights	 Taking account of EMA's business needs and resulting organisation of meetings (from Monday morning until Friday afternoon) all days of the week excluding Saturdays have been included 	• N/A
Number of direct flights	 Average number of daily direct flights from the other MSs to the candidate host MS The number of locations reached by two flights per week on two separate days (to allow for inbound and outbound travel for experts), from Sunday to Friday Autumn business period schedule using the week 8-13 	<u>Google OPX Express API</u>

Criterion 2: Accessibility of the location		
	October 2017 since this represents, taking into account past experience, a week with many meetings organised at EMA involving a large amount of experts	
International flight connections		
Parameter	Methodology used	Public information source used, where relevant
 See section on flight connections within the EEA for the parameters used, where relevant As regards the non-EU countries, only Japan (i.e. Tokyo) and USA (i.e. Washington) have been considered 	See above, where relevant	See above, where relevant
Availability, frequency and duration o	f public transport connections from the proposed airport(s)) ² to the location
Parameter	Methodology used	Public information source used, where relevant
 Overall journey time using public transport from the proposed airport(s) to the location 	 Different types of public transport mentioned in the MS offer, i.e. train, metro, bus, shuttle bus The public transport connection is from the proposed airport(s) to the location. If the offer mentions connection to the city centre, the travel time needed from the city centre to the location is added The frequency of any means of public transport 	 Information provided in the MS offer <u>Google Maps APIs</u>

² As proposed in the MS offer.

Criterion 2: Accessibility of the location			
	The shortest duration of public transport from the proposed airport with the highest flight connection to the location		
Accommodation facilities for experts	Accommodation facilities for experts		
Parameter	Methodology used	Public information source used, where relevant	
Available hotels in the candidate host city	 Only hotels mentioned in the offer within a walking distance radius (0-2km) of the proposed location of the new EMA premises are considered. Quantity and quality of the hotels must be mentioned Quality of the hotels: only 3 and 4* hotels are included due to the EMA hotel reimbursement ceiling 	Information provided in the MS offer	

Criterion 3: Existence of adequate education facilities for the children of EMA staff		
Parameter	Methodology used	Public information source used, where relevant
Types of schools in the candidate host city	 All types of schools have been considered, i.e. European (European and European accredited) schools, International (only schools offering the international baccalaureate), European oriented schools (such as French, German, British etc.) 	 Individual school websites British, German and French embassies websites for each location Agence pour l'enseignement Français à l'étranger (<u>http://www.aefe.fr/</u>) <u>https://www.auslandsschulnetz.de</u>

Criterion 3: Existence of adequate education facilities for the children of EMA staff		
Availability of sufficient education	 Does the offer mention capacity to absorb EMA staff school	
facilities in the candidate host city	children (~600) in current and future schools Information provided in the MS offer	

Criterion 4: Appropriate access to the labour market, social security and medical care for both children and spouses/partners of EMA staff		
Tolerant and open socio-cultural environment		
Parameter	Methodology used	Public information source used, where relevant
Regardless of religion or sexual orientation acceptance of all modern family structures, in particular LGBT equal rights and protection under national law for LGBT persons	Registered partnerships available under national law	www.europa.eu/youreurope/citizens/family/couple/registered-partners
Access to social security and medical care		
Parameter	Methodology used	Public information source used, where relevant
Arrangements in place for providing access to social security and medical care	Same access for EMA staff members and extended family members is available as for nationals of the candidate host MS	Information provided in the MS offer

Criterion 4: Appropriate access to the labour market, social security and medical care for both children and spouses/partners of EMA staff		
Access to the labour market		
Parameter	Methodology used	Public information source used, where relevant
 Job opportunities for EMA staff spouses/ partners 	 Job opportunities support is provided by the candidate host MS 	Information provided in the MS offer