‘Patients First’

Perspective on EMA relocation

October 2017

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About FUNDAMED

Fundamed www.fundacionfundamed.org is a non-profit organization set up to promote debate and analysis on the fundamental issues of healthcare at the global level. Its objectives include the recognition of best practices through the announcement of awards, the promotion of studies and analysis of relevant health issues and the fostering of debate by health officials at local and European level. Fundamed's Scientific Committee is made up of experts of recognized academic and scientific prestige. Fundamed reports are made under the most demanding quality standards, and aim to provide rigorous information that helps health decision-making. Fundamed is a member of the European Public Health Alliance www.epha.org and among its objectives is to help build a Europe with better health in its policies.

TABLE OF CONTENTS

ABBREVIATIONS

BCP: Business continuity plan

EC: European Commission

EMA: European Medicines Agency

EU: European Union

EFPIA: European Federation of Pharmaceutical Industries and Associations

FTEs: Full Time Equivalents

MEB: Medicines Evaluation Board

MS: Member States

EXECUTIVE SUMMARY

Patients First
Perspective on EMA relocation

Background

- 19 cities that offered to host the EMA after Brexit.
- The European Commission (EC) will be considering 5 specific criteria to decide.

‘Patients First’ perspective on EMA relocation

- The Patients First perspective is focused in a quali-quantitative analysis of those criteria that put the patient’s safety and access to medicines in the spotlight.

Conclusion

- Fundamed consider that just 3 cities candidates would ensure a smooth transition that benefit patients and guarantee the continuity of EMA business on time to avoid high risks.

Barcelona

Amsterdam

Milan

Vienna

Copenhaguen

1

2

3

4

5

Statement

- Patients should be the main concern in the EMA relocation decision. Fundamed is focused in this issue and **‘Patients First’** is the embodiment of this idea.

Criteria analyzed from a Patients First perspective

1: Continuity
2: Location accessibility
3: Building and infrastructure

- From a patients first focus, criteria should give a high weigh to candidates that:
  - Guarantee that citizens are the real benefited from the continuity of the EMA activity: **pharmacovigilance**, **evaluation** and **approval** of **innovative treatments**.
  - Facilitate the continued progress on a number of **public health** initiatives.
  - Take into account the support of the **local medicines agency**.
  - Consider the **employees preferences** to **relocate** to ensure the continuity.
  - Guarantee a fast, smooth and efficient transfer to the **new building**.

1. INTRODUCTION

Subsequently United Kingdom decided to withdrawal the European Union and the Brexit begins, 19 cities that offered to host the EMA. For that decision the European Commission (EC) will be considering 5 specific criteria.

The aim of this report is consider the patients needs, because patients should be the main concern in the EMA relocation decision. For this purpose the Fundación de Ciencias del Medicamento y Productos Sanitarios (Fundamed) has priotizied the criteria that should affect them most. 'Patients First' is the embodiment of this idea.

The Patients First perspective is focused in a quali-quantitative analysis of those criteria that put the patient's safety and access to medicines in the spotlight. Thus, the criteria analyzed from a Patients First perspective are: 1) Business Continuity; 2) Location and accessibility; 3) Building and infrastructure.

Patients First perspective analyse those criteria that put the patient's safety and access to medicines in the spotlight

In conclusion, from a Patients First focus, criteria should give a high weigh to candidates that guarantee that citizens are the real benefited from the continuity of the EMA activity.

Fundamed is an organization formed and supported by prestigious professionals, experts, scientists and relevant companies of the Spanish health sector. Its constitution as an organization occurred in 2001 in an environment of important changes that affected the global pharmaceutical sector in general and Spanish in particular. At present, Fundamed promotes initiatives around research and innovation, patient associations and their participation as well as sustainability.

1.1. Background

The United Kingdom withdrawal from the European Union has trigger the competition for hosting European agencies located there as the European Medicines Agency (EMA).

The European Commission established the process recommended for reaching the decision of the remaining 27 Member States on where the EMA should have its seat after the United Kingdom's withdrawal from the Union.

There have been 19 cities that offered to host the EMA (Amsterdam, Athens, Barcelona, Bonn, Bratislava, Brussels,

Bucharest, Copenhagen, Dublin, Helsinki, Lille, Malta, Milan, Porto, Sofia, Stockholm, Vienna, Warsaw and Zagreb).

1.2. Methodology

The patient first criteria are considered in a quali-quantitative analysis on the most relevant criteria to assess the impact on the safe and timely access to the medicines for patients.

The assessment is based on the information provided by the candidates of the Member States that presented their offers to host the European Medicines Agency (EMA) and that were assessed by the European Commission and also the survey on the staff preferences to relocate published by EMA (September 2017). Finally it has been consulted the assessment prepared for the EFPIA on this issue and other relevant information published by the official portals and media reporting.

1.3. Structure of the report

This document is organized in 5 chapters. First chapter includes an introduction on the background and the aim of this report. The chapter 2 refers the work of the European Medicines Agency (EMA) and all its activity areas as well as its plan for continuing its work. Chapter 3 explain the process to decide EMA relocation and the criteria considered by the EC. Chapter 4 analyses the need of putting the Patients First perspective on the top of the decision making process, describes the Fundamed criteria and analyse the candidates level of comply. Chapter 5 is the conclusion of the analysis.

2. THE WORK OF THE EMA

The European Medicines Agency evaluates, is the agency that supervises and monitors the safety of medicines developed by pharmaceutical companies for use in the EU Member States. Since its establishment in 1995 EMA has recommended approximately 1.000 medicines to the European Commission for a marketing authorisation for all EU Member States. Many of these medicines are complex biological molecules, including biotechnology products and cell- and gene therapy products. EMA's annual budget exceeds 300 million.

The Agency is funded by the European Commission and fees charged to the pharmaceutical industry. Today, almost all new or innovative medicines are submitted to EMA for assessment.

According to EU law, most of these medicines cannot be assessed at national level. These medicines benefit patients suffering from cancer, diabetes, neurological disorders, infectious diseases or autoimmune disorders.

2.1. Activities of the Agency

2.1.1. Facilitate development and access to medicines

EMA is committed to enabling timely patient access to new medicines, and plays a vital role in supporting medicine development for the benefit of patients. The Agency uses a wide range of regulatory mechanisms to achieve these aims, which are continuously reviewed and improved. To achieve this, the Agency uses a wide range of regulatory mechanisms: support for early access, scientific advice and protocol assistance and pediatric procedures. EMA also provides scientific support for advanced-therapy medicines, orphan designation of medicines for rare diseases, scientific guidelines on requirements for testing the quality, safety and efficacy of medicines and the Innovation Task Force.

2.1.2. Support for research and innovation in the pharmaceutical sector

Also the support for research and innovation in the pharmaceutical sector is an issue where EMA has a role, as well as the promotion of innovation and the development of new medicines by European micro-, small- and mediumsized-enterprises

2.1.3. Evaluate applications for marketing authorization

EMA's scientific committees provide independent recommendations on medicines for human and veterinary use, based on a comprehensive scientific evaluation of data. The Agency's evaluations of marketing-authorisation applications submitted through the centralised procedure provide the basis for the authorisation of medicines in Europe. They also underpin important decisions about medicines marketed in Europe, referred to EMA through referral procedures. The agency also coordinates inspections in connection with the assessment of marketing-authorisation applications or matters referred to its committees.

2.1.4. Monitor the safety of medicines

Monitoring and supervising the safety of medicines that have been authorised in the EU, is one of the main activities of EMA, in order to ensure that their benefits outweigh their risks.

EMA works by: developing guidelines and setting standards; coordinating the monitoring of pharmaceutical companies' compliance with their pharmacovigilance obligations; contributing to international pharmacovigilance activities with authorities outside the EU; informing the public on the safety of medicines and cooperating with external parties, in particular representatives of patients and healthcare professionals.

2.1.5. Provide information to healthcare professionals and patients

The Agency publishes clear and impartial information about medicines and their approved uses. This includes public versions of scientific assessment reports and summaries written in lay language.

On September 2017 EMA initiated a BCP to deal with workload implications of the Agency relocation after Brexit

2.2. EMA Business Continuity plan

On September 2017 EMA initiated a business continuity plan (BCP) to deal with the uncertainty and workload implications linked to the United Kingdom's withdrawal from the EU and the Agency's relocation.

EMA launched its BCP focusing on prioritising the Agency's activities. EMA plan focuses on the need to keep its most important functions running smoothly and be ready to cope with potential significant staff loss during the transition to a new location. The plan has three priority levels for EMA's activities according to their impact on public health and the ability of the Agency to function properly (Table 1).

In case of a business continuity situation the Agency will first decrease the activities and therefore the number of Full Time Equivalents (FTEs) spent on category 3 (lowest priority), followed by category 2 (medium priority) and lastly by category 1 (highest priority).

Table 1. EMA Priority Activities and need of resources

Priority level	Activities	Full Time Equivalents (FTEs) required
Category 1	**The highest prioritised activities are Category 1** activities which are either directly related to the assessment and safety monitoring of medicines or vital for maintaining the infrastructure of the European medicines regulatory network. These activities include for example coordination of actions to protect the safety of patients in all EU Member States.	462 FTEs
Category 2	**Medium priority, Category 2** activities are public health and strategic activities such as the contributions to fight against antimicrobial resistance, collaboration with health technology assessment bodies and initiatives in the area of availability of medicines.	140 FTEs
Category 3	**Category 3** activities are the lowest priority and cover governance and support activities such as corporate governance, audits, participation in and organisation of meetings and conferences.	110 FTEs

Source: Adapted from EMA.

In order to achieve the EMA 2017-2018 strategic objectives, initiatives and performance indicators EMA will try to continue its work. However, this plan would be applied in the undesirable situation of not be able to operate for as long as possible under a "business as usual" scenario.

To continue to perform just its most highly prioritised activities, EMA needs 462 full time equivalent (FTE) staff, almost 50% of its current employees. It needs another 140 FTE to carry out medium priority work and a further 110 to continue to perform its lowest priority activities.

3. THE DECISION ON EMA RELOCATION: THE EUROPEAN COMMISSION

For the decision on EMA relocation the European Commission (EC) established 6 specific criteria, in order to assess the suitability of the new headquarters offer. These criteria are:

1. The assurance that the agency can be set up on site and take up its functions at the date of the United Kingdom's withdrawal from the Union

This criterion concerns in particular the availability of appropriate office premises in time for the Agency to be able to take up its functions at the new location at the withdrawal date. This should include the necessary logistics and sufficient space for offices, meeting rooms and off-site archiving, high-performing telecommunication and data storage networks as well as appropriate physical and IT security standards.

2. The accessibility of the location

This criterion concerns the availability, frequency and duration of flight connections from the capitals of all EU Member States to the airports close to the location, the availability, frequency and duration of public transportation connections from these airports to the location, as well as the quality and quantity of accommodation facilities. In particular, the criterion implies the capacity to allow for the continuation of the volume and intensity of current meeting activities of the Agency.

3. The existence of adequate education facilities for the children of agency staff

This criterion concerns the availability of multi-lingual, European-oriented schooling that can meet the needs for education facilities for the children of the current staff as well as the capacity to meet also the future education needs.

4. Appropriate access to the labour market, social security and medical care for both children and spouses

This criterion concerns the capacity to meet the needs of the children and spouses of the current as well as of future staff for social security and medical care as well as the availability to offer job opportunities for these.

5. Business continuity

This criterion is relevant given the critical nature of the services provided by the Agencies and the need therefore to ensure continued functionality at the existing high level. The criterion relates to the timeframe required to fulfil the four criteria above.

It concerns amongst other things the ability to allow the Agencies to maintain and attract highly qualified staff from the relevant sectors, notably in case not all current staff should choose to relocate. Furthermore, it concerns the capacity to ensure a smooth transition to the new locations and hence to guarantee the business continuity of the Agencies which should remain operational during the transition.

6. Geographical spread

This criterion relates to the agreed desirability of geographical spread of the agencies' seats, and to the objective set in December 2003 by the representatives of the Member States, meeting at Head of State or Government level and confirmed in 2008.

Final decision on EMA relocation will occur 20 November when Member States will vote and they must consider relevant criteria

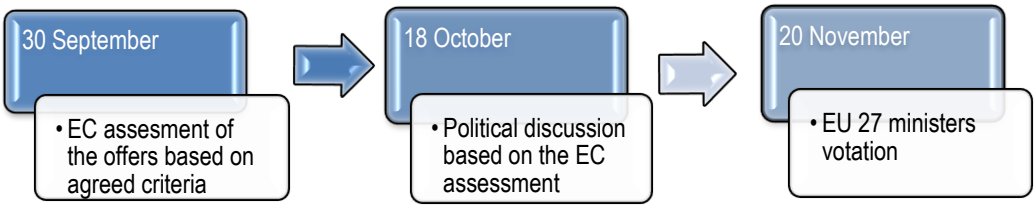
3.1. The process to decide the new EMA location

The Commission will also consult the Agencies regarding technical requirements. For each Agency, the Commission will analyse the extent to which each offer meets the criteria and how it addresses the stipulated specific issues.

EC shall submit the evaluation of the offers to the Secretary-General of the Council, who will make it public and forward them to the Member States. On 18 October, European Council celebrated a “political debate” on the candidates that explained their bids while technical criteria were assessed by EU 27.

However, final decision will occur in 20 November, when the States will have to vote choosing the EMA destination. Is important to point out that, although the final decision is free and secret, Member States must consider all relevant criteria to decide their vote.

The timeline until the final decision is the following:



4. TOWARDS PUTTING THE PATIENTS FIRST PERSPECTIVE ON THE TOP OF THE DECISION MAKING PROCESS

As the final decision on EMA relocation will be adopted by Member States, that decision must be informed and assuming all the risks and consequences for the citizens.

The Fundación de Ciencias de Medicamentos y Productos Sanitarios (Fundamed) is focused in the important: analyzing and considering the influence of the relocation process in the wellbeing of the patients. 'Patients First' is the embodiment of this idea. If the decision should put European patients first, the criteria that should have a high weigh are those that:

- Can guarantee that citizens are the real benefited from the continuity of the EMA activity as pharmacovigilance, evaluation and approval of innovative treatments.
- Can facilitate the continued progress on a number of public health initiatives.
- Take into account the support that local medicine agency can give to the EMA along the transition process.
- Consider the current employees preferences to relocate in order to avoid the staff drain and ensure the continuity of the EMA business.
- Ensure a fast, smooth and efficient transfer to the new location. Include the proposal of a building ready, highly prepared, accessible and well located.

Putting patients first and ensuring the continuity of the EMA business is a differentiating fact for the candidates to host the EMA that must priories an availability of medicines and a smooth transition. Thus, Fundamed analysis promotes that the technical aspects must be taken in account before the political

aspects in the final decision. So that, the availability of medicines and innovative treatments for patients, must be the highest priority.

4.1. The 'Patients first' Fundamed criteria

The Fundamed criteria for the EMA relocation will value those candidates that are in the best conditions to ensure that the work that EMA has to do doesn't affect to the patient's rights.

Patients First criteria will value candidates that are in the best conditions to ensure EMA relocation won't affect to the patient's wellbeing

Therefore, according to the European Commission the 'PATIENTS FIRST' CRITERIA and its parameters are:

Criteria 1: Continuity

1.1. Workload capacity

1.2. Staff available and projected:

a) Current employees of the local agency and expected

b) Risk of staff loss

1.3. Appropriate access to the labour market, social security and medical care.

Criteria 2: Location accessibility

2.1. Flight connection

2.2. Public transport

2.3. Accommodation capacity

2.4. Climate conditions

Criteria 3: Building and infrastructure

3.1. Building availability

3.2. Size & facilities

3.3. Relocation plan

4.2. Impact of EMA relocation on the access to medicines and safety of patients. The analysis.

After reviewing the results of the EMA analysis on the offers, there are just 5 cities that could guarantee that the Agency can maintain the activity in the short term. Although the scenario "as business as usual" is not realistic, the adaptation must be done in a way that the access to medicines and the safety of patients is not endangered in an irresponsible manner. For that

reason, the selected cities for the analysis are: Amsterdam, Barcelona, Copenhagen, Milan and Vienna, which comply with the highest level of guarantees.

4.2.1. Criteria 1: Continuity

This criteria refers to the ability of the local agency for assuming the EMA work in a period of time. This period must guarantee the full recovery on the shortest period.

These criteria include the number of projects co-leading with EMA and the national agency workload capacity. Thus, it is considerate the current collaboration between agencies and the availability of the national agency to support the daily work of EMA.

Workload capacity

Countries analyzed show a different level of cooperation between the national Agencies and EMA. This parameter is fundamental for the continuity of the Agency's work, and there are some countries that clearly risk the EMA activity ant the patient's safety and others that are safer.

The differences are quite relevant. While in 2016 The Netherlands lead or work with EMA in 114 human or veterinary drug committees or workshops and Spain in 168, Denmark just reached a maximum of 71. In the case of Italy the quantity was 95 that year what place this country in eighth position for its workload. In the case of committees are quite relevant. Austria led or co-led 150 human or veterinary drug committees or workshops in 2016. Finally, Denmark achieved a total of 71 human or veterinary drug committees or workshops in 2016.

One of the main concerns for EMA is the current number of employees that will be able of assume the work of the Agency

Staff available and projected: Current employees of the local agency and expected and risk of staff loss

Additionally, the staff available and projected is also a relevant factor, as one of the main concerns for EMA is the current number of employees that will be able of assume the work o the Agency itself. That includes the local agency staff and the expected collaborators.

The candidates in a best position are Spain and Sweden. Thus, the Spanish Medicines Agency has 363 experts plus 226 members and 137 external experts. Additionally, the Spanish

Ministry announced that there will hire to 40 new staff. In total the Barcelona candidacy counts on 766 staff to support the work of the EMA. Swedish agency has almost 750 workers at the agency, most of them are pharmacists and doctors.

In the middle are Italy and Denmark with approximately 400 employees in their respective agencies. And the Netherland agency, that has 300 professionals and experts working for the Medicines Evaluation Board (MEB). At the end of the ranking there is Austria, with a national Agency that has 208 staff in total.

As the EMA business continuity plan consider, it will be necessary to deal with the uncertainty and workload implications linked to the United Kingdom's withdrawal from the EU and the Agency's relocation. In this manner, EMA established the highest priority activities as the assessment and safety monitoring of medicines as vital to maintaining the infrastructure of the European regulatory system for medicines. That includes, for example the coordination of actions to protect the safety of patients in all EU Member States and the inspections across the EU.

Fundamed values the risk of EMA staff loss through the evaluation of the availability to move to each of the candidate cities

Also is vital to consider the risks of staff drain due to the new EMA location. One of the scenarios that EMA take into account considers the staff losses and how these may affect the delivery of its activities. Unexpected higher, faster or more permanent loss of staff as a consequence of the Agency's relocation may lead to a situation in which EMA's operations can no longer be maintained.

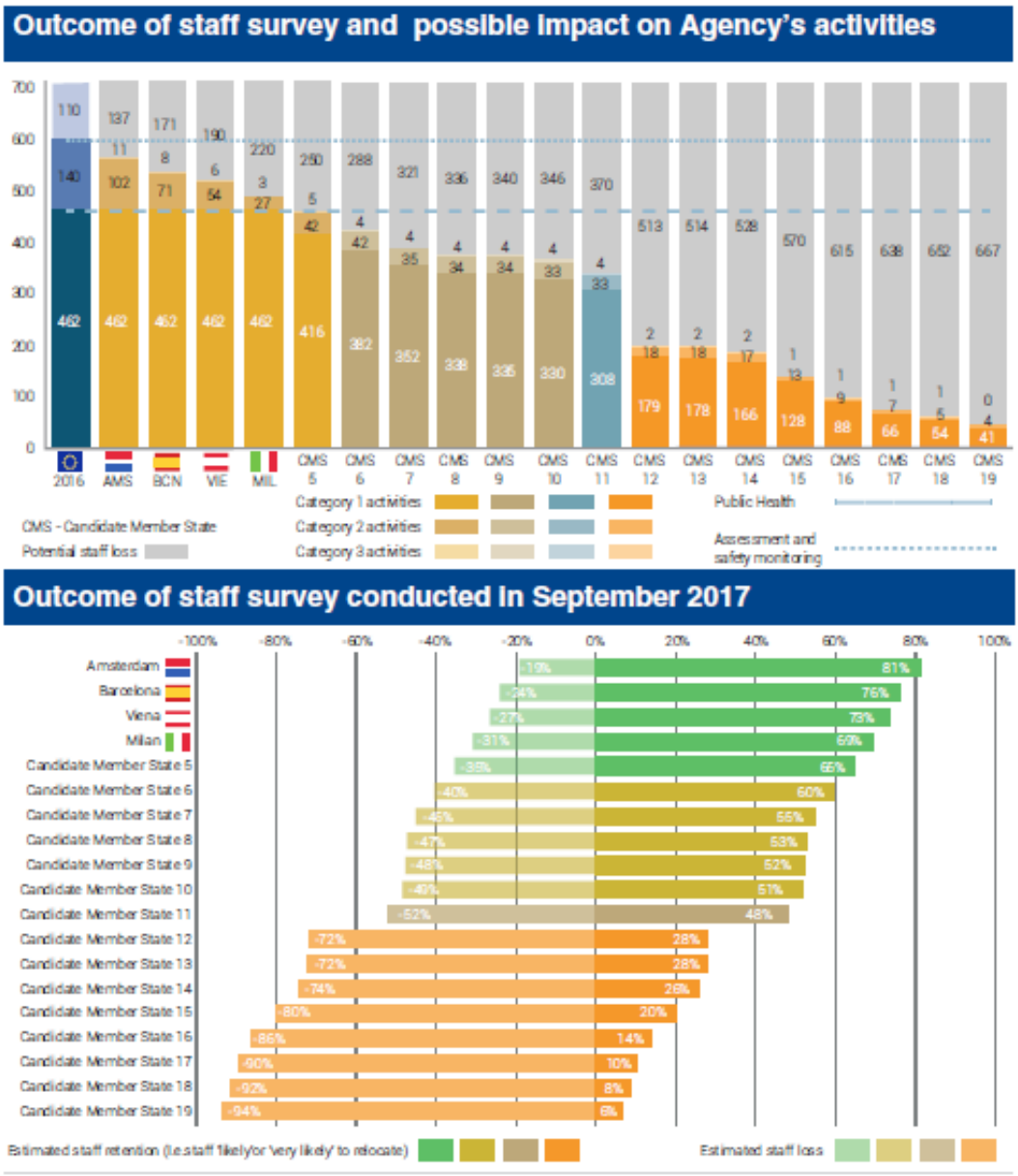
Fundamed values the risk of EMA staff loss through the evaluation of the availability to move to each of the candidate cities. It must be highlight that the EMA is the biggest body set to leave Britain after it quits the EU and employs 890 staff. The published data of the poll made for EMA to its employees, questioned to staff about the availability to move to other Member States that are candidates to hosting EMA. Among other variables, the EMA assessed compliance with deadlines for relocation, technical conditions, proposed building, as well as services and facilities.

Amsterdam, Barcelona and Copenhagen, are the 3 cities where the employees would move likely or most likely

The results (Figure 1) showed that Amsterdam, Barcelona and Copenhagen, become the podium of cities where the employees would move likely or most likely. The EMA workers'

preference list also includes France, and Germany, all of which are candidates to become the European Agency's new headquarters. On the other hand, the Eastern countries, in the last positions, were not a desired destination of the current employees.

Figure 1. Poll on the preferences for living of the EMA staff



Source: Adapted from EMA / Reuters.

Consequently, although the top five candidates ensure an average retention of staff of 73 per cent, in the case of

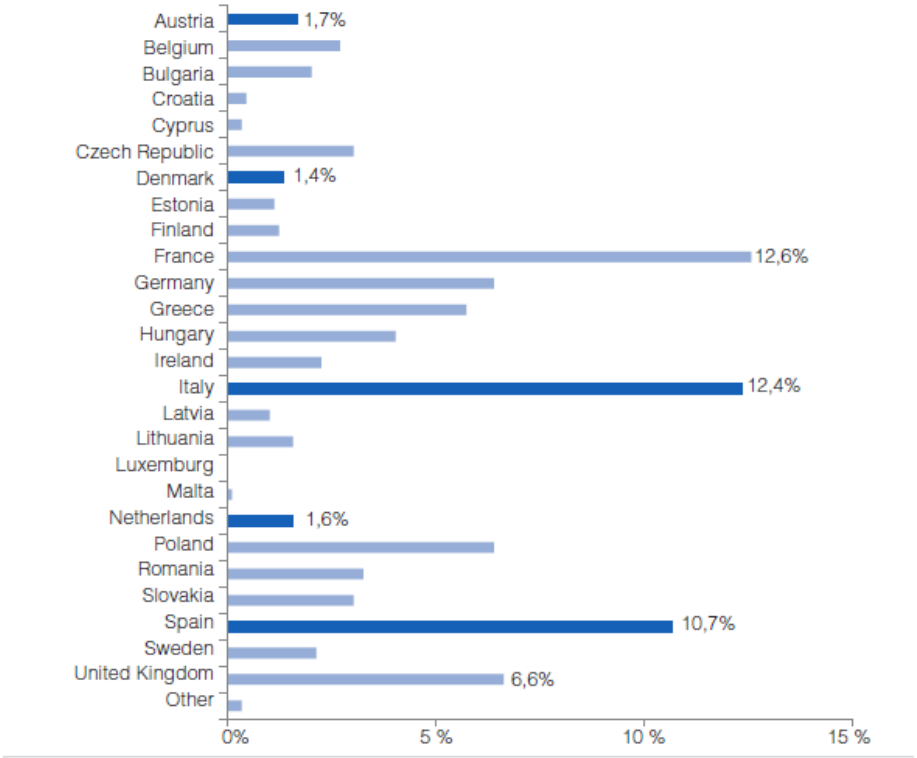
Copenhagen would be about a 65 per cent (Figure 1). That is, by fine-tuning, only the first three ensure that the agency is fully operational with a delay that does not exceed an irreversible deadline. In fact, choosing some other headquarters for the agency would jeopardize the functionality of the EMA in the years after Brexit.

In addition, the EMA assessment considered the parameters which measure the ability to continue the activity once the United Kingdom leaves the European Union. Pharmacological surveillance, approval of innovative drugs and marketing authorizations are some of the tasks that the new headquarters must guarantee. However, some candidates have not been able to demonstrate it, as in the case of Vienna, which is off the best rated for failing to meet the needs of services and facilities required.

The highest percentage of staff national origin belongs to France, Italy and Spain that achieve a 35,7%

Furthermore there are a number of citizens from European countries that are already employees from EMA (Figure 2). The data reveals that the highest percentage of staff national origin belongs to France, Italy and Spain that achieve a 35,7% Of the total of EMA employees. This could be a relevant matter in the final decision to move to another country for the employees and their families. So the proximity to these locations could influence the professional's and the current and future staff decision.

Figure 2. National origins of the Agency staff



Source: Adapted form EC.

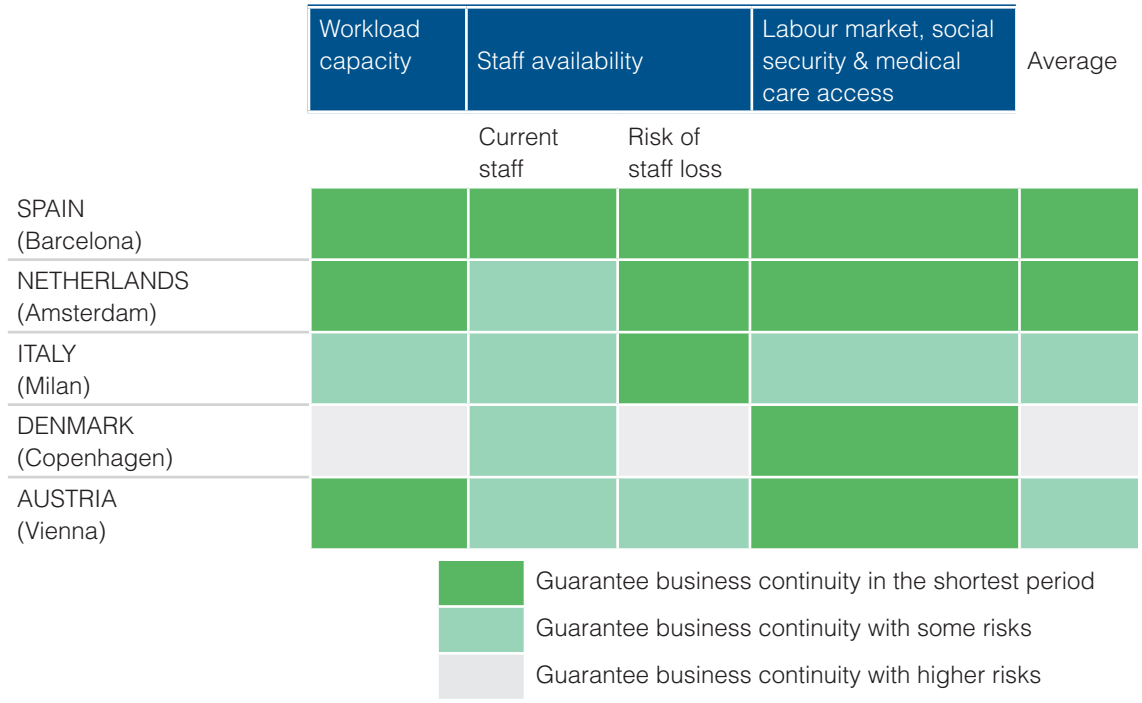
Appropriate access to the labour market, social security and medical care

As the candidates' offers states in their bids, most of the cities offer employment support. That is the case of Barcelona, Amsterdam, Vienna or Copenhagen. However, Milan offer does not includes employment support, what can interfere in the access to the labour market for the families of the EMA employees.

One offer does not include employment support, what can interfere in the access to the labour market for the EMA employees and their families

The access to the social security system and medical care is also one of the attractive facilities considered for current and future employees in de decision on moving. Considering the access to social security and medical care for spouses and children, most of the offers indicate these services; however the case of Milan is the only case where employment support is not stated in the offer.

Table 2. Criteria 1: BUSINESS CONTINUITY



Source: Fundamed.

4.2.2. Criteria 2. Location accessibility

This criterion analyzes the connectivity and the accessibility to the EMA location, as well as the climate conditions that will determine the staff decision of moving to the candidate cities.

In the cases of Amsterdam, Copenhagen and Vienna have excellent flight connection with the rest of Europe through their main cities and its airports and with the rest of the world. However, in the cases of Milan and Barcelona, the connection with international airports is very good.

Also the public transportation is a parameter well valued in the five candidates because the availability, frequency and duration of public transport connections between the airports is satisfactory and can guarantee the normal daily transportation.

Accessing to a new location depends also on climate conditions, because is valuable issue for the staff when making the decision of where to live. This parameter has considered average of annual temperatures and annual precipitation. Thus

the cities with the best climate conditions for living are Milan and Barcelona. Nevertheless the rest of the criteria could compensate the lack of a more steady weather.

Table 3. Criteria 2. LOCATION & ACCESIBILITY

	Flight connection	Public transport	Accommoda-tion capacity	Climate	Average
SPAIN (Barcelona)					
NETHERLANDS (Amsterdam)					
ITALY (Milan)					
DENMARK (Copenhagen)					
AUSTRIA (Vienna)					

Excellent fulfillment of the criteria
Very good fulfillment of the criteria
Good fulfillment of the criteria

Source: Fundamed.

4.2.3. Criteria 3: Building and infrastructure

Building availability

Building availability refers to the diary working that depends on this relevant criteria. The infrastructures and the space must be ready to facilitate that the new location incorporates the necessary staff and resources and the diary tasks. In this parameter, only Barcelona offers a building already built even when the other candidates explain that their respective buildings will be ready on time to assume the daily work of EMA on time.

Only Barcelona offers a building that is already built. However, the other candidates explain that their respective buildings will be ready on time

Size & facilities

The building availability for a quick transition is another parameter that can concern patients in order to guarantee a safe and smooth transition. All the candidate cities accomplish the requirement of the minimum building size.

Relocation plan

Organising the stages for the transition period is a must to assure that the new location will be ready on time. Only 3 candidate's cities offer a detailed timeframe to achieve EMA relocation, which is the case of Amsterdam, Barcelona and Milan. Both of them proposed to be ready for Q1/19. A governance structure is outlined and strong procurement support is provided adaptation work and physical removal will be provided of the appropriate support.

Just 3 candidate's cities offer a detailed timeframe to achieve EMA relocation, which is the case of Amsterdam, Barcelona and Milan

However, in the case of Milan there could be necessity of adaptation works due to the dispersion of the meeting rooms throughout the building, which may create logistical issues due to operational needs.

In the case of Vienna, its weak spot is the lack of procurement support by the Member State that is absent in the offer, as well as happens in the Copenhagen proposal. Additionally the Danish city raises security concerns with regards to multi-tenancy and public access to the building. In addition, the multi-access points for staff also raise logistical issues.

Table 4. Criteria 3. BUILDING & INFRASTRUCTURES

	Building availability	Size & facilities	Relocation Plan	Average
SPAIN (Barcelona)				
NETHERLANDS (Amsterdam)				
ITALY (Milan)				
DENMARK (Copenhagen)				
AUSTRIA (Vienna)				

Building available and comply infrastructure requirements

Building in project and/ or deficit in requirements

Source: Fundamed.

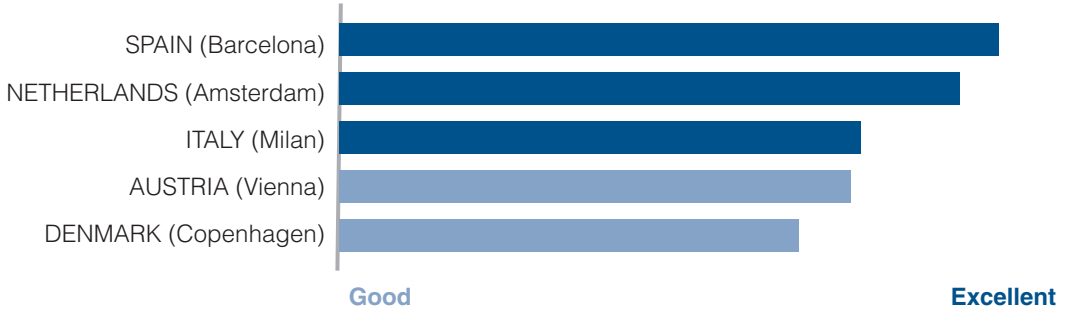
5. CONCLUSION

In order to be sure that the business continuity of the EMA work is maintained in excellent conditions, there are only 3 cities that could guarantee this condition. Barcelona, Amsterdam and Milan would be able to avoid an irreversible damage to the EMA work continuity.

These candidates are on the top of the ranking provided by the analysis of the criteria that assure the continuity of the EMA most relevant activities related to the access to safety and innovative medicines.

Therefore, choosing a different new location for the most relevant body that assess the safety of medicines, approve and procure the access for patients to the ultimate and most advances treatments would be an incomprehensible and questioned decision.

Figure 3. Patient's First criteria classification of EMA candidates



Source: Fundamed.

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7. TABLE OF FIGURES

8. TABLE OF TABLES

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