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Assessing the impact of the disruption from the relocation of the European Medicines Agency

Final report

Confidential - Embargoed

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Abbreviations

ADR	Adverse drug reaction
ATMP	Advanced Therapy Medicinal Product
CAT	Committee for Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
COMP	Committee for Orphan Medicinal Products
CRA	Charles River Associates
EBA	European Banking Authority
EC	European Commission
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
GCP	Good clinical practice
GLP	Good laboratory practice
GMP	Good manufacturing practice
IT	Information technology
MA	Marketing authorisation
MS	Member States
NCAs	National Competent Authorities
OMP	Orphan Medicinal Product
PRAC	Pharmacovigilance Risk Assessment Committee
SMEs	Small and medium-sized enterprises

Executive Summary

Charles River Associates (CRA) was asked by EFPIA to conduct an evaluation of the impact of the potential disruption arising from the relocation of the European Medicines Agency (EMA) away from London to a new location in the European Union (EU). This has two objectives:

- Provide information to the industry on the risk to business continuity and the corresponding impact on public health (including patients and healthcare systems) resulting from the relocation of EMA
- Review the bids of each of the candidate countries, taking into account Step 1, and provide an overall assessment of the suitability of each bid

The EMA is a decentralised agency of the EU which evaluates and authorises medicinal products and has been housed in London's Canary Wharf since 1995. As the UK has notified the European Council of its intention to leave the Union, it is necessary to move EMA to another location within the Union's territory.[1]

The purpose of this report is to consider, from an industry perspective, the potential risk to business continuity as a result of the relocation, in regard to the different activities of EMA as well as the corresponding impact on public health (including patients and healthcare systems). To determine the impact on the industry and knock-on impact on public health, we have used the evidence from academic literature and interviews.

Overview of EMA activities

The EMA is responsible for protecting and promoting both public and animal health in 28 EU Member States, as well as in the countries of the European Economic Area (EEA), by ensuring that all medicines available on the EU market are safe, effective and of high quality. Our analysis, however, has focused on the activities of the EMA associated to human rather than animal health. EMA coordinates the evaluation and monitoring of centrally authorised products and national referrals, develops technical guidance and provides scientific advice to sponsors. EMA has an important coordinating role across the European Medicines Regulatory Network, and provides the administrative and scientific secretariat to all of the main scientific committees and working parties, giving the agency access to a pool of over 4,500 experts across the network.[2]

Figure 2 maps out the range of activities conducted by EMA. Based on EMA's clustering of these activities, these can be grouped into five categories, each containing sub-activities, as listed below.

1 Council of the European Union (2017). Procedure leading up to a decision on the relocation of the European Medicines Agency and the European Banking Authority in the context of the UK's withdrawal from the Union, 22/06/2017, http://www.consilium.europa.eu/en/press/press-releases/2017/06/22-euco-agencies-relocation/

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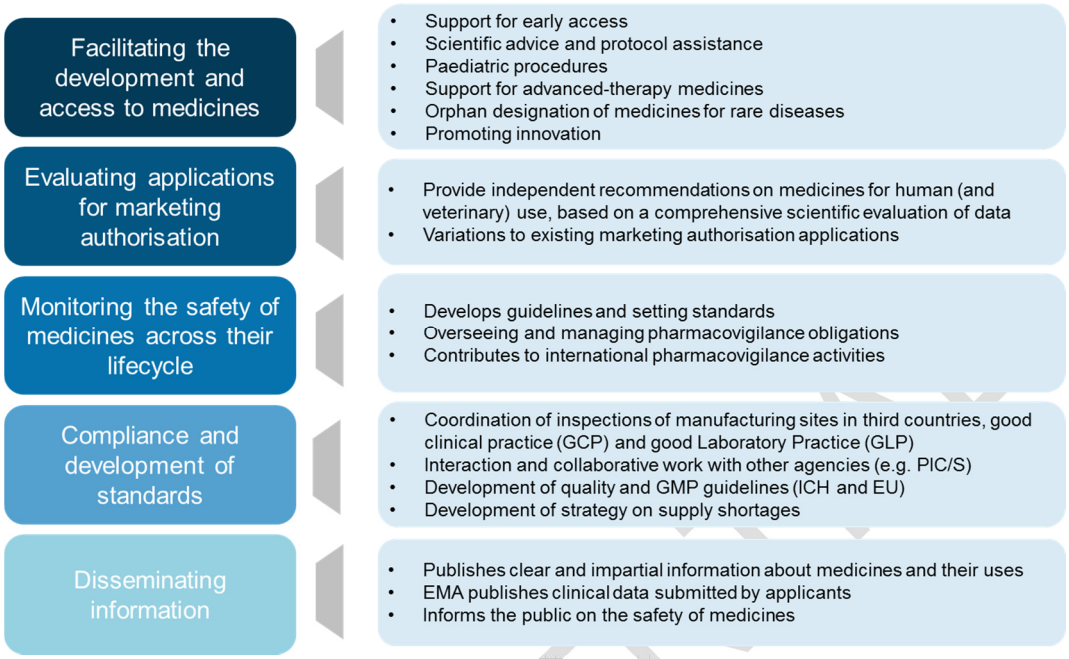
Figure 1: List of EMA activities by group



Source: Developed from the description of activities by European Medicines Agency[3]

There are two significant ways that relocation could impact on the activities of EMA. Firstly, the location of EMA could impact its ability to coordinate the network of expertise and to call on expertise. Secondly, the relocation could jeopardise the EMA's ability to retain its own capabilities, affecting its contribution to the process. Base on input from regulatory experts, we have largely focused this report on the ability of EMA to retain the key staff to perform their activities.

For each of EMA's five key activities, CRA has identified the risk of disruption by assessing the importance of EMA internal expertise. We have used two approaches to collect qualitative and quantitative data on this:

1. Review EMA staff involved in activities and the types of skills that are vital to performing these activities, together with volume and timelines for processing
2. Interview regulatory experts, capturing their perspectives on the impact of relocation

Step 1: Impact of EMA relocation on risk of business discontinuity

This section of the report takes into account the role that EMA plays within each group of activities presented above, the level of human and capital resources associated to this, and the level of expertise and experience involved in conducting EMA's operations.

We first mapped the processes and activities to the departments within EMA that carry them out. We then drew on interviews with regulatory experts to determine how interchangeable these resources are, as well as to what extent these roles can be backfilled through secondments or new hires. This provided us with a risk of discontinuity.

3 European Medicines Agency – Website: About Us: What we do. Accessible at http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000091.jsp&mid=WC0b01ac0580028a42

Next, we considered the impact of these activities on the pharmaceutical industry and, subsequently, their impact on public health (this can be described as a chain of causality). The premise is that loss of staff and other resource constraints can impact efficiency and business continuity, which in turn can have implications for both patients and industry; for example, if there is a delay in marketing authorisation (MA), this delays the marketing of a new product and can impact patients by delaying their access to medicines.

As highlighted in Table 3, according to our analysis, two areas of activity have the greatest risk of disruption due to the relocation of EMA, these include:

- EMA's evaluation of applications for MA,
- Post-marketing activities, particularly pharmacovigilance.

Any disruption to these activities are likely to have direct implications for patients unless they are adequately prioritised and contingency staff (seconded national experts) are provided.

Failure to ensure adequate staff in these areas could mean that EMA is not able to abide by the legal procedural timelines – or "timeouts" are used inappropriately. This could lead to delays in patient access to new life-saving therapies and a potential dysfunctioning in the coordination of pharmacovigilance activity. This would mean that when adverse effects and toxicity occur, such information may not be analysed and communicated effectively across the European network and this could lead to a slower reaction to the monitoring, detection and assessment of adverse drug reactions (ADRs) across Member States.

Disruption to some activities could have knock-on effects on other activities. This is the case, for example, for the paediatric department, because of the role of the paediatric investigation plan (PIP) in MA, and disruption of which may impact the MA process. Additionally, the workload in some departments may increase as a result of Brexit, such as MA variations or a requirement for new site inspections, which also has implications on business continuity.

We find the other three areas of activity have less of a direct impact on business continuity or public health. However, a significant concern is that activities that are important in the medium term may be neglected. The result of this would be that Europe "falls behind" the rest of the world in terms of regulatory science; there is especially concern about falling behind Japan and the US. This could have a particular impact on investments into the European market and in particular the growth prospects of small and medium-sized enterprises (SMEs).

Table 1: Ranking of activities by their level of risk of disruption and impact on business continuity and public health

	Risk of disruption and impact on business continuity	Impact on public health
Evaluating applications for marketing authorisation	Loss of expertise and procedural experience in this area would lead to a significant level of disruption to EMA's ability to coordinate the CHMP and could jeopardise the entire MA process	This would result in a direct impact on patients' ability to have timely access to new treatments
Monitoring the safety of medicines across their lifecycle	Risk of disruption in this area is high, due to management of the IT systems and the high volume of safety signals across the network	This disruption may impact critical safety functions of the EMA and lead to delays in the identification, management and communication of product safety issues
Facilitating the development and access to medicines	There is a moderate risk of disruption in this sector. Some areas directly link to the longer-term marketing authorisation process. In other cases, the damage is on longer-term EU competitiveness	This would not result in direct impact on patients in the short-term. However, this could have a knock on effect on other parts of the regulatory process and on long-term incentives to innovate
Compliance & development of standards	This area has a lower risk of disruption as the activities require fewer EMA resources. However, some scientific and regulatory expertise, such as the coordination of inspections or the involvement in ICH are an essential support function	This would have less of an immediate effect on the public compared to the previous activities
Disseminating information	Whilst these activities are completely dependent on EMA staff, this segment is based on reports already generated through other EMA activities, and has the least potential to cause problems with business discontinuity	Many stakeholders would regard the dissemination of information very useful in driving standards and meeting regulatory requirements, but is not critical in terms of public health

High impact on public health | Medium impact on public health | Low impact on public health

Source: CRA analysis

Step 2: Assessment of locations

The second step of this report is a qualitative assessment of the 19 official bids submitted by countries wishing to host the EMA.[4] To do this, we use the European Commission's criteria and set out how these criteria can be turned into a series of metrics (also taking into account the industry priorities in terms of business continuity and corresponding impact on public health). We then apply this template to the different bids for the relocation of EMA.

4 European Council of the European Union. Offers to host the European Medicines Agency (EMA). Available at: http://www.consilium.europa.eu/en/policies/relocation-uk-based-agencies/ema/

Each bid will be assessed by the European Commission (EC) against the official criteria it has set out.[5] The aim of this analysis is to assess each country in terms of how it meets EC's requirements, also taking into account the industry's priorities for business continuity. We have introduced metrics resulting from the interviews with industry regulatory experts, including their experience in relocating of activities (e.g. day trip connectivity and the ability to get the last flight out after the business day).

We have also drawn on the insights from Step 1, with additional considerations to ensure business continuity and operational efficiency of the Agency, for example the ability to hire staff aware of the required regulatory expertise, to draw staff from other agencies (by using secondments) or to hire experts from companies. We also draw on standard external metrics of quality of life such as Eurostat's "Quality of Life Index" or the Lancet's "Healthcare Access and Quality Index", which are both important factors in assessing the attractiveness of the location. The result of our analysis is a set of metrics that reflect both the EC criteria and the priorities of business continuity (see Table 2Table 5). The metrics reflect the importance of the location to supporting staff retention and being able to backfill any staff losses if there is a gap during the transition period.

Table 2: List of indicators used for the bid analysis

European Commission criteria	Linkages to continuity of EMA's activities	Indicators
Adequate office logistics	Sufficient capacity of office space that meets all of the requirements for EMA to carry out its activities (e.g. expert meetings and IT/systems management)	• Location ready to use at the time of Brexit • Meeting room facilities • Records management and archiving • IT capacity and data servers • Security infrastructure
Accessibility of the location	Ability of EMA to access external expertise across Europe for regular meetings. If experts are unable to travel efficiently, this could lead to substantial delays in activities	• Direct daily travel connections and proximity to other EU capitals • Feasibility of day trips from other EU cities • Feasibility of getting the last flight out after the business day • Resiliency of transport connections • Sufficient hotel capacity
Adequate education facilities	Suitable education facilities for children of EMA staff in order to support staff retention	• Number of international or European schools • Capacity of schooling system i.e. availability of places to meet EMA requirements
Labour market, social security and medical care	The attractiveness of the location for EMA staff and their families from a quality of life perspective in order to support staff retention	• Employment opportunities for spouses • Availability and quality of housing • Healthcare Access and Quality (The Lancet Healthcare Access and Quality Index • Size of international population • Overall life satisfaction (Eurostat QoL index)

5 Council of the European Union (2017) Procedure leading up to a decision on the relocation of the European Medicines Agency and the European Banking Authority in the context of the UK's withdrawal from the Union, 22/06/2017, http://www.consilium.europa.eu/en/press/press-releases/2017/06/22-euco-agencies-relocation/

Business continuity	Ensuring the location offers minimal disruption to EMA's activities during the transition period Potential for new location to facilitate staff retention, and as a backup, provide a talent base to backfill any staff shortages after relocating	• Support provided by host government during the transition period to guarantee the daily operations of EMA • Size, capacity and location of national competent authority • Skill set from local life sciences industry relevant to EMA's activities

Source: CRA analysis

Using the indicators listed above, we have undertaken an assessment of the official bids submitted for hosting the EMA against the EC's criteria. The aim of this analysis is not to make a specific recommendation of which city is best suited to host the agency, but to provide an overall assessment of the suitability of each bid. We therefore focus on identifying whether some of the conditions of each location would increase the risk of disruption and jeopardise business continuity, for example, by putting at risk EMA's ability to retain its current staff or attract new employees with relevant expertise. The results of our analysis is presented in Table 6 at the end of this report. We have adopted a traffic light system where green dots indicate that the bid meets or exceeds the criteria; amber dots indicate that the criteria is met but with some limitations, and red dots indicated that the bid does not meet the criteria and this could represent a risk to business continuity.

1. Introduction

Charles River Associates (CRA) was asked by EFPIA to conduct an evaluation of the impact of the potential disruption arising from the relocation of the European Medicines Agency (EMA) away from London to a new location in the EU. This has two objectives:

- Provide information to the industry on the risk to business continuity and the corresponding impact on public health (including patients and healthcare systems) resulting from the relocation of EMA
- Review the bids of each of the candidate countries against the official criteria set by the European Commission taking into account the risks to business continuity

1.1. Background

The European Medicines Agency is a decentralised European Union (EU) body which evaluates and authorises medicinal products within the EU and the European Economic Area (EEA) and has been housed in London's Canary Wharf since 1995. It is responsible for coordinating scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products for human and veterinary use.[6]

As the United Kingdom (UK) has notified the European Council under Article 50 of the Treaty on European Union of its intention to leave the Union, it is necessary to move EMA to another location within the Union's territory.[7] At the European Council (Art. 50) on 29 April 2017, the EU institutions outlined their intention to work out a transparent procedure that should ensure that a decision can be taken on the new seats of the decentralised agencies – EMA and the European Banking Authority (EBA) – in the autumn of 2017. The procedure for the relocation of the agencies was endorsed in the margins of the European Council (Art. 50) in June and a final decision should be reached on 20 November 2017.

The purpose of this report is to consider from the industry perspective the potential risk to business continuity resulting from relocation of the different activities of EMA, as well as the corresponding impact on public health (including on patients and healthcare systems). This will serve to provide decision makers additional considerations from a pharmaceutical industry perspective on the decision about where to relocate the EMA, and avoid any arbitrary decisions that could lead to being located in a country that would jeopardise its activities and, in turn, compromise companies' ability to deliver safe and effective medicines to patients.

1.2. Methodology

As set out above, this research is divided into two main steps:

- Step 1: Provide information on the risk to business continuity and the corresponding impact on public health.

6 EMA (2017) "About us", accessible at: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/08/WC500211862.pdf

7 "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" www.consilium.europa.eu/en/meetings/european.../22-euco-procedure-agencies_pdf/

- Step 2: Review the bids of each of the candidate countries, taking into account Step 1, and provide an overall assessment of the suitability of each bid.

Step 1 analysis starts with a review of how EMA works today and then considers the factors that affect the risk to business continuity and its impact on the pharmaceutical industry and, subsequently, the impact on public health (this can be described as a chain of causality). To do this, we reviewed the existing literature on the operations of EMA (especially from EMA itself but also drawing on the academic and grey literature – a total of 20 publications) to understand how it works today, and we mapped out its key activities and the role of internal EMA staff versus experts from Member States.

We developed a set of hypotheses about the potential impact of disruption to EMA's activities for the industry and tested these through a series of interviews with regulatory and business experts. Interviews were conducted with experts from GSK, Pfizer, MSD, and Sanofi, and wider comments were provided by EFPIA Regulatory Committee. Recently, EMA itself has published its plan for ensuring that disruption is minimised.[8] We have not taken this into account in our assessment of risk of disruption but compare the priorities set out by the EMA against the results of our analysis.

To undertake Step 2, we started from the six criteria set out by the European Commission.[9] For each of the EU's criteria, we have set out a template with metrics that allow countries to be compared on an objective basis. These have been augmented with criteria that take into account the risks to business continuity. We populated the template using information from the bids[10] and from public sources.

1.3. The structure of the report

The rest of the report is structured as follows:

- In Chapter 2, we set out the role of EMA and the framework for considering the risk to business continuity.
- In Chapter 3, we review the activities of EMA and prioritise them in terms of risk to business continuity.
- In Chapter 4 we use augmented EU criteria to assess the different bids for the relocation of EMA.

8 "EMA prepares for Brexit" Available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/07/news_detail_002789.jsp&mid=WC0b01ac058004d5c1

9 Council of the European Union (2017). Procedure leading up to a decision on the relocation of the European Medicines Agency and the European Banking Authority in the context of the UK's withdrawal from the Union, 22/06/2017, http://www.consilium.europa.eu/en/press/press-releases/2017/06/22-euco-agencies-relocation/

10 The bids were published on 1 August 2017 and are available at http://www.consilium.europa.eu/en/policies/relocation-uk-based-agencies/ema/

2. Overview of EMA activities

To assess the risk of disruption from relocation we need to start from how EMA works today and then consider what could happen following relocation.

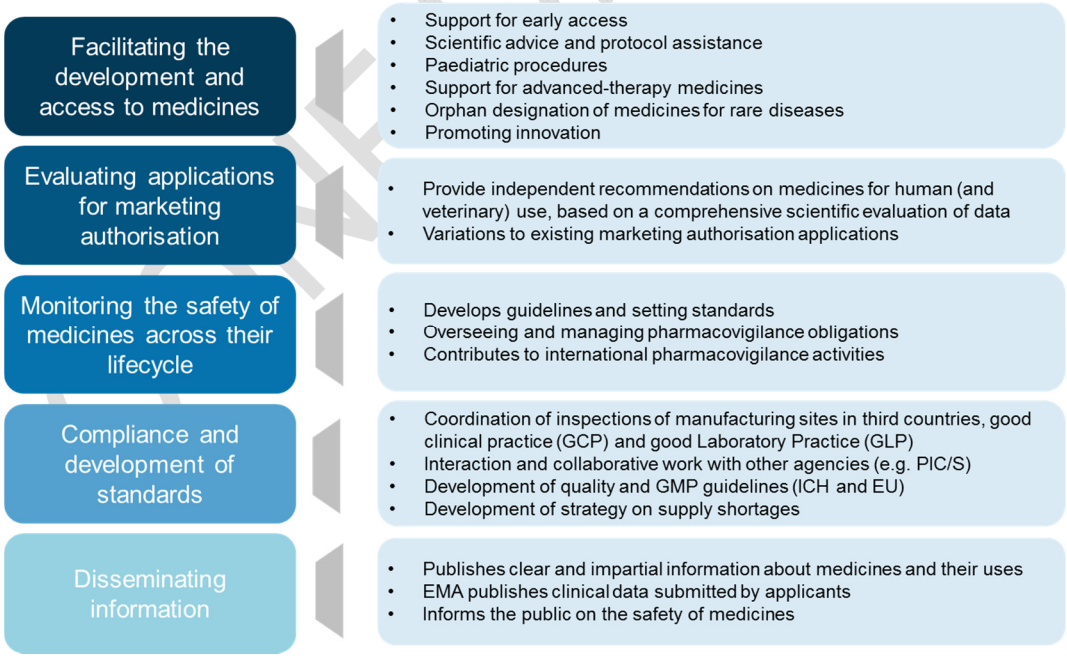
2.1. Overview of EMA activities

The EMA has responsibility for the protection and promotion of public and animal health in 28 EU Member States, as well as in the countries of the EEA, by ensuring that all medicines available on the EU market are safe, effective and of high quality. Given our focus on human health, the analysis has focused on the activities of the EMA associated to human rather than animal health.

2.1.1. What EMA does

EMA coordinates the evaluation and monitoring of centrally authorised products and national referrals, developing technical guidance and providing scientific advice to sponsors. Its scientific assessment of medicines is undertaken via a network of experts across the EU, drawing on resources of National Competent Authorities (NCAs) of EU Member States. Figure 2 maps out the range of activities conducted by EMA. Based on EMA's clustering of these activities, they can be grouped into five categories, each containing sub-activities, as listed below.

Figure 2: List of EMA activities by group



Source: Developed from the description of activities by European Medicines Agency[11]

[11] European Medicines Agency – Website: About Us: What we do. Accessible at http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000091.jsp&mid=WC0b01ac0580028a42

2.2. Business continuity risks

In order to identify which of these fields of activities are most likely to be impacted by disruptions, we consider some of the factors that are likely to cause disruptions. There are two significant ways that relocation could impact on the activities of EMA. Firstly, the location of EMA could determine its ability to coordinate the network of expertise and its ability to call on expertise. Secondly, the relocation could jeopardise the EMA's ability to retain its own capabilities, affecting its contribution to the process.

2.2.1. Coordinating the network and the capabilities of the host country

One possibility is that the location is important as it allows physical proximity to expertise in the host country. EMA has a series of core committees that are responsible for its activities. Focusing on human medicines, these include the Committee for Medicinal Products for Human Use (CHMP), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO) and the Pharmacovigilance Risk Assessment Committee (PRAC) and Committee for Advanced Therapies (CAT). Relocation could have an impact on these committees' activities.

EMA has an important coordinating role across the European Medicines Regulatory Network, and provides the administrative and scientific secretariat to all of the main scientific committees and working parties, giving the agency access to a pool of over 4,500 experts across the network.[12] Therefore the coordination of this network not only requires accessibility, but the support of EMA staff.

Interviews with regulatory experts indicated they were in strong agreement that EMA works as a decentralised agency using a network of experts from across the EU. The availability of expertise from the network does not depend on the proximity of external experts (i.e. academics), national regulatory agency experts or industry or patient representatives. This was not a factor affecting EMA's operation. Thus, external expertise could be flown in to EMA's new location (provided it had sufficiently good transport connections) if and when required, and that this would not cause disruption to the system. The importance of the local NCAs and local industry as a source of expertise was therefore discounted as a risk to business continuity.

2.2.2. The role of EMA's staff and internal capability

The second risk is retention of the EMA's internal capability. EMA staff support its activities including administrative and procedural aspects of EU law related to the evaluation and safety-monitoring of medicines in the EU. As of December 2016, the staff numbered 897 men and women, working across 7 divisions as well as other support functions, as shown in Figure 3 below.

The interviews with regulatory experts indicated that although EMA staff do not necessarily undertake all of the activities – for example, the assessment of application for marketing authorisation (MA) – their key role is coordinating the network of expertise and ensuring that the specific EU procedures under EMA's responsibility are followed. The workload of EMA staff requires a lot of very skilled scientific administrators and secretariats to help

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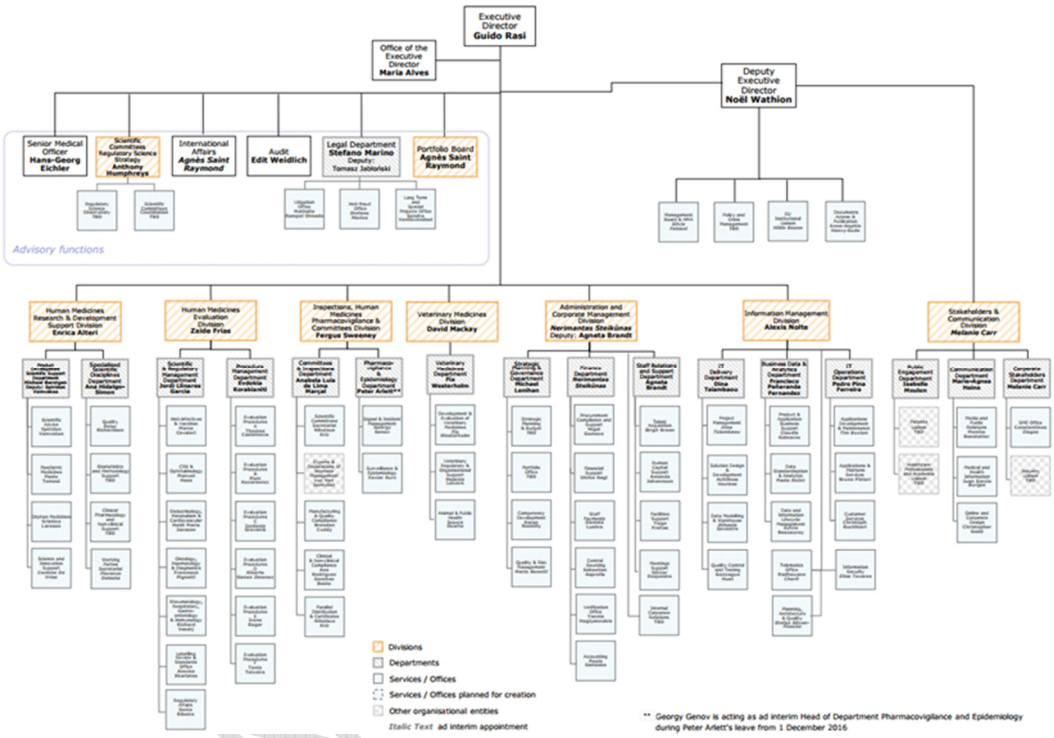
organise and coordinate the process. This involves accessing necessary external expertise.

All interviews have reported that "scarce" staff – those key to activities and difficult to replace – are those with:

- Scientific and medical expertise
- Experience with EMA processes and regulatory procedures

Figure 3: EMA organisation chart



Source: European Medicines Agency

It is therefore the premise of this analysis that EMA's ability to retain or attract highly competent staff and internal subject matter experts to manage the central regulatory system is the primary factor in assessing the potential for disruption. This forms the backbone of all activities, and if this is majorly disrupted then this can impact the completion of tasks.

IT infrastructure

EMA's information technology (IT) capacity is important in terms of sharing and communicating information. A lot of activities are dependent on these resources, such as the EudraVigilance database for pharmacovigilance. In the interviews there arose some concerns relating to risks from relocation. In particular, it was noted that EMA's current technology platform relies on a server-based system rather than cloud-based services, with the result that relocation has risk in terms of business continuity. One key consideration would therefore be the portability of EMA IT systems.[13] However, the interviewees agreed it is unaffected by the relocation destination per se, providing the process is appropriately managed and there is limited impact from staff resource constraints. The opportunity to

13 Interview with regulatory expert

contract out for IT expertise and capability is possible in all countries in the EU – this was therefore seen as a relatively low consideration in the decision of where to relocate.

Given the structure of EMA and our concern for public health, the analysis has focused on the potential disruption linked to relocation of EMA staff to a new location.

2.3. A framework for assessing the risk to continuity

For each of EMA's five key activities, CRA has identified the risk of disruption by assessing the importance of EMA internal expertise. We have used two approaches to collect qualitative and quantitative date on this:

3. Review EMA staff involved in activities:
    - Use the EMA organisation chart to map to activities
    - Review the professional background of "experts"
    - Assess whether experts are attracted to the local market
4. Interview regulatory experts, capturing their perspective on the impact of relocation by asking the following questions:
    - What activities are the most reliant on support from EMA staff?
    - Which of these activities rely the most on scientific and medical experts at EMA?
    - Which types of internal scientific and medical experts are going to be most difficult to retain?
    - What impact does each activity have on other EMA activities?

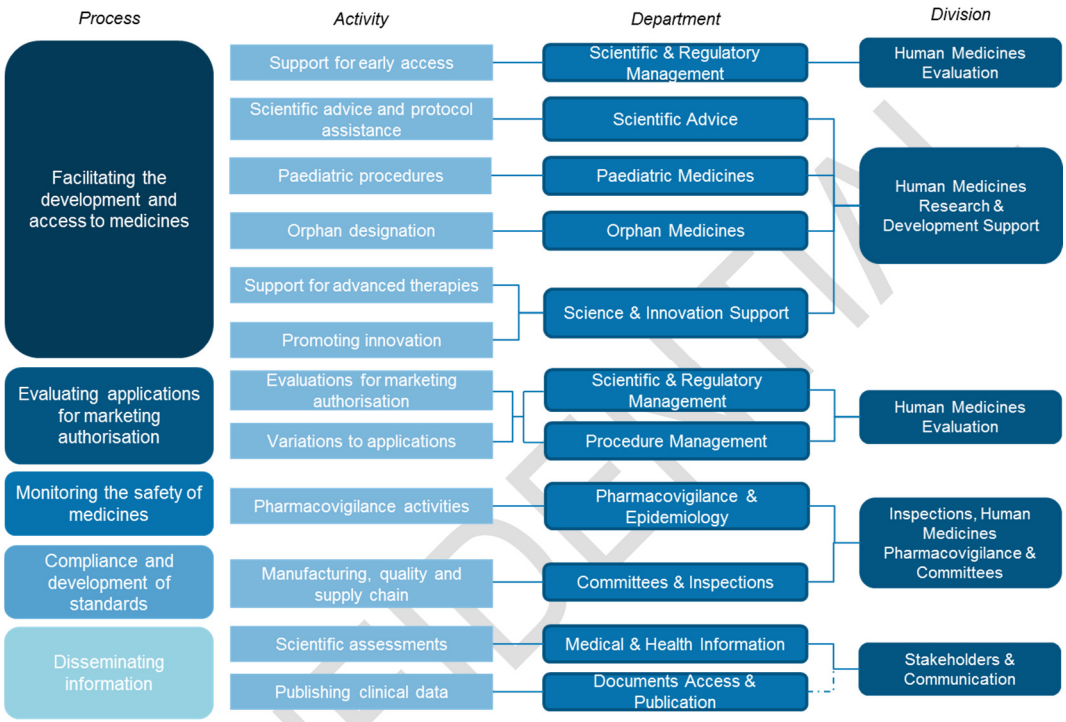
To assess the impact on the industry and knock-on impact on public health, we have used the evidence from academic literature and interviews.

3. Impact of EMA relocation on risk of business discontinuity

This section considers the role that EMA plays within each group of activities presented in section 2.1.1, and the level of the activity based on the 2016 annual report, but also the level of expertise and experience involved in conducting EMA's operations.

The first step was to map the processes and activities to department within EMA, as shown in Figure 4 below.

Figure 4: Mapping activities to EMA's organisation chart



Source: CRA analysis

We then drew on interviews with regulatory experts to determine how interchangeable these resources are, as well as to what extent these roles can be backfilled through secondments or new hires. This provided us with an estimated risk of discontinuity. Next, we considered the roles of these activities and the impact on the pharmaceutical industry and, subsequently, the impact on public health (this can be described as a chain of causality). The premise is that loss of staff and other resource constraints can impact efficiency and business continuity, which in turn can have implications for both patients and industry; for example, if there is a delay in MA, this delays the marketing of a new product and impact patients through delays in getting access to medicines.

3.1. Facilitating the development of and access to medicines

The EMA plays a vital role in supporting medicine development for the benefit of patients and also seeks to foster patients' early access to new medicines that address public health needs. The Agency uses a wide range of regulatory mechanisms to achieve these aims:

- Support for early access
- Scientific advice and protocol assistance
- Paediatric procedures

- 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
- The Innovation Task Force

Generally these processes are high volume, short procedures, thus a drop in staffing levels would lead to disruption and impact EMA's ability to process applications in the short-term. During 2016, together with the relevant committees, EMA reviewed 549 paediatric investigation plans (PIPs) and 329 applications for orphan designation.[14] EMA staff play a key role in assessing and coordinating these activities. In some areas, the teams are small and this make them particularly reliant on a small number of experts with procedural and scientific expertise. It has been argued that losing staff in these areas could lead to a higher level of disruption.[15]

EMA's in-house experts who coordinate the provision of scientific advice have more general scientific understanding. In 2016 EMA finalised 439 requests for scientific advice and 122 requests for protocol assistance.[16] These are very high volume and rapid turnover procedures, and the delivery could be severely compromised in the event of staff losses. Additionally, the experience of the overall MA process that will subsequently be applied to the medicines is vitally important, making staff expertise regarding the regulation and the internal processes key to this activity.

Impact on business continuity and on public health

All of the activities within this group are important functions of EMA, but some activities are arguably more critical to business continuity in the short and medium term.

- The paediatric procedures result in authorisation of a PIP, which is a necessary condition for getting a marketing authorisation.[17] The risk of disruption to business continuity is therefore high as the inability to process compliance checks may act as a roadblock for other processes. This could have further implications on industry through delaying development of new medicines and initiation of clinical trials.

- Scientific advice is intended to ensure that developers perform the appropriate tests and studies in patients in order to collect robust high-quality data for the MA application. There is evidence that this improves the MA process[18], but there are no legal requirements for this activity. Disruption to EMA's ability to deliver scientific advice increases probability of non-compliance with regulatory requirements when applying for

14 EMA Annual Report 2016

15 Interview with regulatory experts.

16 EMA Annual Report 2016

17 All applications for MA for new medicines have to include the results of studies as described in an agreed PIP, unless the medicine is exempt because of a deferral or waiver. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000608.jsp&

18 For early scientific advice by regulatory, analysis has shown that products undertaking early scientific advice have higher probability of achieving regulatory approval. See for example "Deerfield Institute – EuropaBio Report on Regulatory and HTA scientific advice for small and medium enterprises", March 2015.

MA or extension of indication. There is also the likelihood for implications much further down the line (e.g. knock-on effects within the MA process) and this can lead to delays in processing the MA.

- The process for assigning an orphan medicine designation (which typically occurs some years before MA) or advanced therapy designation is likely to have a smaller impact on business continuity. These are often not a business critical activity and would not be a roadblock in the approval process. However, they are important for some companies such small and medium-sized enterprises (SMEs) in terms of driving a business case for development and access to finance.[19]

- PRIME enables early dialogue and accelerated assessment of promising new medicines that have the potential to address patients' unmet needs and entry points for this is prior to initiation of confirmatory trials.[20] If EMA is unable to adequately resource PRIME, companies could miss the window of opportunity to apply for PRIME. Additionally, disruption to EMA's support around early access programmes (PRIME, Adaptive Pathways) may in the long term reduce the competiveness of the EMA and the EU regulatory system as a whole. These schemes are important in ensuring Europe remains advanced in terms of regulatory science.[21]

A significant concern is that Europe will fall behind Japan and the US and the rest of the world in terms of regulatory science. Regulatory predictability is important to all companies but particularly SMEs involved in biotech product development and this is likely to have a long-term impact on incentives to innovate.

There is a risk of disruption in this activity. This will not result in direct impact on patients, however there may be delays in development of medicines that could have global implications. Additionally there may be knock-on effects on other parts of the regulatory process and on long-term incentives to innovate as well as the overall competitiveness of the EU regulatory system (e.g. impact on SMEs).

3.2. Evaluating applications for marketing authorisation

EMA's scientific committees provide independent recommendations on medicines for human and veterinary use, based on a comprehensive scientific evaluation of data.[22] The EMA coordinates CHMP in its scientific evaluation of new treatments, with input from various other internal committees. The CHMP also establishes Scientific Advisory Groups (SAGs) to provide advice in connection with the evaluation of specific types of medicines or treatments. These committees consists of independent experts from each of the 28 Member States. While the initial assessment reports are written by the Rapporteur and other committee members (within the national agencies), EMA's in-house scientific experts

19 Miller, K. L. (2017). 'Do investors value the FDA orphan drug designation?', *Orphanet Journal of Rare Diseases,* 12(1): 114.

20 Jordi Llinares and Zahra Hanaizi (2016) "Regulatory brief on new PRIME scheme", 3 October 2016

21 "EMA Launches its own Fast Track for Breakthrough Therapies, from the Clinic" Denise Neves Gameiro, 9 March 2016.

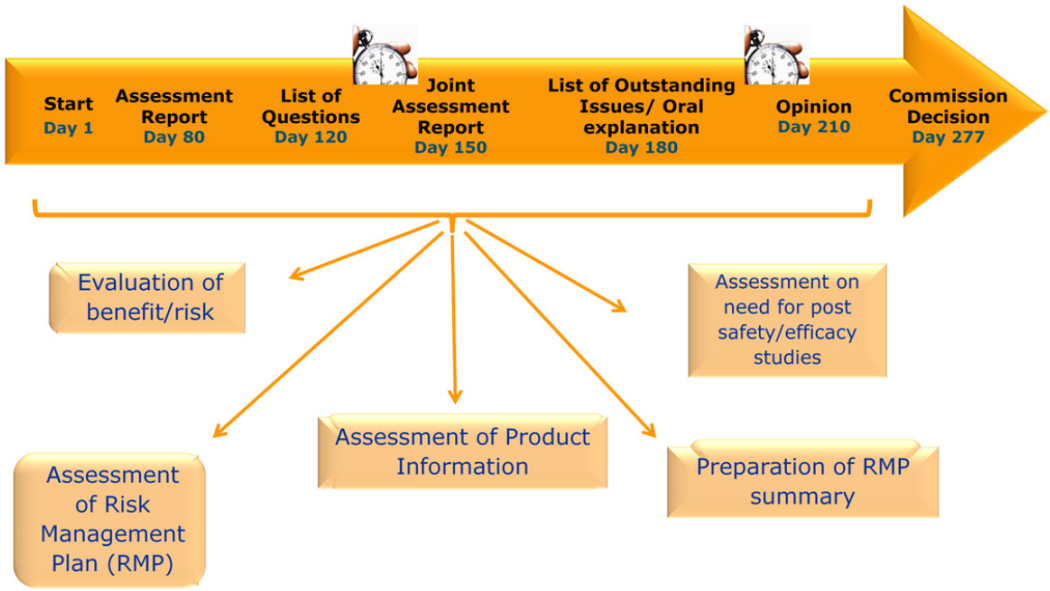
22 European Medicines Agency (2017) About Us: What we do ; http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000091.jsp&mid=WC0b01ac0580028a42

act as coordinators and project managers (coordinating the activities of national experts and providing assistance in drafting the report). If the CHMP is not coordinated effectively by EMA due to staff losses, this could delay CHMP recommendations on MA.

Industry experts reported that EMA's scientific administrators largely bring the procedural expertise and regulatory knowledge that are used across tasks, as the scientific expertise mainly comes from Member States. More importantly, they coordinate the expertise amongst the assessors and ensure compliance with procedures (in line with EU regulation) and make sure the process is conducted efficiently. As illustrate in **Error! Reference source not found.**, the level of scientific expertise is also needed as a prerequisite for carrying out this role. The combination of scientific and medical specialists (oncology, endocrinology etc.) combined with the regulatory knowledge is critical in this activity. In fact, the Human Medicines Evaluation Division is the largest in terms of staff numbers at EMA.

As illustrated in Figure 5**Error! Reference source not found.**, assessing an application for a new medicine can take up to 210 'active' days. In 2016 there were 85 MAA pre-submission meetings, 114 initial MAs and 6,204 post-authorisation application variations (including line extensions, Type IB, Type II and Type IA variations).[23]

Figure 5: EMA timeline of assessment of an application for marketing authorisation



Source: European Medicines Agency[24]

In case of loss of staff, hiring new scientific in-house experts (without understanding of the science or regulatory requirements) would slow down the operative efficiency of the MA process. In terms of redeveloping these competencies, one regulatory expert suggested that it would take approximately 1-2 years for new specialised staff to become fully confident in terms of the regulatory and procedural requirements. The most likely source for backfilling these positions is from NCAs, who would be aware of the EMA process

23 EMA Annual Report 2016

24 European Medicines Agency (2017) Overview of the centralised procedure at the European Medicines Agency http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2016/02/WC500201043.pdf

through their involvement as national experts in the process. Hiring from the industry has constraints due to EMA's conflict of interest policy, for example it is not possible to work on a submission from the company that an industry expert has left for a period of time.

Impact on business continuity and on public health

EMA's evaluations of MA applications (submitted through the centralised procedure) provide the basis for the authorisation of medicines in Europe. A high proportion of EMA staff work in this area and have the necessary scientific and procedural expertise. Any potential loss of such combined experience may lead to ineffective coordination of the assessments, and lack of compliance with procedures (in line with EU regulation), and this could significantly disrupt the entire MA approval process. It is a requirement of the MA process that an opinion is provided in 210 days).[25]

Such disruption, both in terms of volume of staff required and the level of expertise, is likely to have a significant impact on the overall MA evaluation process. This could mean failure to abide by the legal procedural timelines or lead to procedural delays in approving new medicines across Europe.

There are also issues surrounding maintenance. The inability to maintain the pace of the MA process in the EU will raise compliance issues for companies. This could lead to delays in communicating safety issues and updating product information. There will also need to be process variations to updates MAs in relation to the UK's withdrawal from the EU, which needs to be factored in the level of activity required.

The evaluation of MAs is also critical to ensure that Europe has a competitive assessment internationally. EMA provides the structure, guidance and coordination in order to carry out the operations. On average, the EMA takes around six months longer than the FDA to approve a new drug or a new indication for a medicine.[26] This in turn could lead to further delays in patient access to new life-saving treatments.

The risk of disruption is significant in this area. The loss of expertise and regulatory experience in this area could jeopardise the entire MA process. The impact to this area could be exacerbated should there be high level of staff loss combined with an increase in industry submissions to changed MAs. This will in turn result in a direct impact on patients' ability to have timely access to new treatments.

3.3. Monitoring the safety of medicines across their life cycles

EMA, in cooperation with member state competent authorities, has the responsibility for maintaining the risk-based programme for routine pharmacovigilance inspections of holders of MAs for centrally authorised products and ensuring its implementation. EMA also plays a key role in the coordination of pharmacovigilance inspections specifically triggered by CHMP and in inspection follow-up.

25 "Overview of Authorisation Procedures for Medicinal Products" http://www.raps.org/uploadedFiles/PDF_Assets/EU%20Fundamentals,%20Ch.%2017.pdf

26 Beishon, M. (2014) "Approval rating: how do the EMA and FDA compare?" *Cancer World*, available at http://www.cancerworld.org/Articles/Issues/58/January-February-2014/Cutting-Edge/637/Approval-rating-how-do-the-EMA-and-FDA-compare.html

The role of EMA has changed over the last five years. The introduction of the Pharmacovigilance Legislation, in 2012, established PRAC.[27] This led to a clarification of the roles and responsibilities of those involved in monitoring the safety and efficacy of medicines in Europe and strengthened coordination and the role of EMA, leading to more robust and rapid EU decision-making.

Overall, in this area, PRAC (composed of national experts) is central to the process. However, EMA staff coordinates the monitoring of pharmaceutical companies' compliance with their pharmacovigilance obligations.[28] EMA's in-house experts need sufficient scientific and medical understanding to process the information correctly, as well as the regulatory experience. If there is a safety signal, they are responsible for ensuring that the necessary process in response to the safety issue is followed, and in 2016 alone EMA reviewed 2,372 safety signals.[29]

The reporting and communication of information on safety issues is important, and EMA provides the link to international databases on a global level. The IT infrastructure is therefore an important component of the system, as are the staff who are able to query the database accordingly based on the scientific and epidemiology requirements.

Impact on business continuity and on public health

Pharmacovigilance is one of the key responsibilities of EMA in terms of safeguarding public health. Significant loss of scientific expertise and IT staff could have repercussions on key activities such the evaluation of safety signals and management of the EudraVigilance database, for example.

Some activities of EMA are also heavily reliant on IT infrastructure, such as EudraVigilance for pharmacovigilance. One key consideration is the portability of EMA IT systems and ensuring that EMA has enough resources to manage this during the transition.

The pharmacovigilance activities and MA activities are interrelated. The consequences of this monitoring may also be impeded as a result of delays to evaluations (loss of staff), as it is important to consider some pharmacovigilance activities are post-authorisation monitoring.

Disruption to pharmacovigilance activities could have a direct impact on public health, as the European Medicines Regulatory Network may not have the most up-to-date information on a medicine's benefits and risks, leading to delays in addressing safety issues.

There is a risk of disruption arising from the management of the IT systems and the management of safety signals across the network if key staff are lost. This disruption may impact critical safety functions of the EMA and lead to delays in the identification, management and communication of product safety issues

27 European Medicines Agency (2012) Press release: New pharmacovigilance legislation comes into operation. Better protection of public health through strengthened EU system for medicines safety. Accessible at: http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2012/07/WC500129311.pdf

28 Interview with EFPIA regulatory expert

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3.4. Compliance and development of standards

The EMA is responsible for harmonising standards set out in EU legislation and guidelines for good clinical practice (GCP), good laboratory practice (GLP) and good manufacturing practice (GMP) for investigational medicinal products.[30] In practice, the responsibility for the inspections regime for manufacturing is handled by Member States; however, EMA has a coordinating role for GMP inspections of manufacturing sites for medicines and develops quality and GMP guidelines (in the EU, and coordinates with other regions through the International Conference on Harmonisation, ICH). IT capacity and system management is also very important within this area, such as monitoring EudraCT and EudraGMP.[31]

In 2016 there were 181 notifications of suspected quality defects and 3,787 certificate requests, of which 487 were urgent requests.[32] If these cannot be processed timely then they can have a knock-on effect that impacts patient's access to safe medicines.

The administrative functions include the Scientific Committees Secretariat, which coordinates the European network of experts across activities. EMA's Committees and Inspections Department, which is primarily to do with compliance, has a relatively high proportion of administrative functions. Activities within this department have a greater reliance on staff with scientific and regulatory expertise, such as manufacturing and quality compliance (for GMP inspections) and clinical & non-clinical compliance (for GCP inspections). These are both essential support functions when issues are identified across the European network.

Impact on business continuity and on public health

Overall this activity is reliant on fewer EMA resources and is has less direct impact on patients when compared to the activities previously discussed. However, it is important to consider how activities in this area can have an impact on others processes. The coordination of EMA's committees forms the backbone for key decisions and the Agency's scientific opinions.

In addition, coordination of inspections has implications for the timing of MA submissions. The coordination of quality defect reports is an important activity for industry to manage batch recall where necessary, as this is essential to safeguard public health.

From a European public health strategy perspective, it is important for Europe to engage in international activities, such as ICH. Without this, global initiatives would be led by the priorities of other regions (in particular, Japan and the US), and Europe's voice would inevitably be given less priority.

This activity requires fewer EMA resources, and therefore the risk of disruptions is relatively lower. However, some scientific and regulatory expertise, such as the coordination of GMP and GCP inspections or the involvement in ICH are an essential support function. This will have less impact on the immediate public compared to the previously discussed activities.

30 European Medicines Agency Website - Research and development: Compliance, accessible at http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001794.jsp&mid=WC0b01ac0580b95063

31 Interview with EFPIA regulatory expert

32 EMA Annual Report 2016

3.5. Disseminating information

EMA publishes information about medicines and their uses as well as guidelines for patients and healthcare professionals. This includes public versions of scientific assessment reports (EPARs), review of patient information leaflets and Summary of Product Characteristics. EMA also publishes clinical data submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure.

The level of activity is high. For example, if we look at the last year, EMA published 71 guidelines and concept papers adopted by CHMP in 2016, and 82 publications by EMA staff members.[33] All these activities are completely dependent on EMA staff and are associated with some scientific and procedural expertise. However, the output in this segment is based on reports already generated through other EMA activities (e.g. MA activity, or facilitating the development of and access to medicines).

The role of EMA staff in this segment largely consists of communication specialists, medical writers, legal and web management expertise. As a result, a large proportion of the EMA staff act in a secretarial capacity – including preparation of product related information for the general public, such as EPAR summaries and safety communications. Management of Early Notification System includes development and distribution of aligned positions of regulatory authorities across the EU. This division is also very important for managing EMA's interaction with patients, consumer organisations and industry.

Impact on business continuity and on public health

This activity has the least potential to cause problems with business discontinuity, however many stakeholders would regard the dissemination of information as highly important for public health.

3.6. Impact on business continuity for industry

In the previous sections, we have set out the risk of disruption and the impact on business continuity within the industry and any corresponding impact on patients. However, we have not taken into account the actions undertaken by EMA to mitigate any disruption.

EMA's business continuity plan

EMA has developed and initiated a business continuity plan to deal with the uncertainty and workload implications linked to the UK's withdrawal from the EU and EMA's relocation.[34] This provides some indication of which activities it will seek to prioritise, as follows:

- **Category 1**, includes the highest priority activities: assessment and safety monitoring of medicines; the infrastructure of the European regulatory system for medicines, including for example the coordination of actions to protect the safety of patients in all

33 European Medicines Agency - Annexes to the annual report of the European Medicines Agency 2016 http://www.ema.europa.eu/docs/en_GB/document_library/Annual_report/2017/05/WC500227333.pdf

34 European Medicines Agency (2017) Press release: EMA prepares for Brexit Business continuity plan aims to preserve Agency's ability to protect public and animal health; accessible at: http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2017/08/WC500232808.pdf

EU Member States, inspections across the EU or maintenance of the functionality and security of critical IT applications used by all Member States.

- **Category 2**, includes activities with the second highest priority: the proactive publication of clinical data, and various initiatives that aim to promote availability of medicines as well as some political priorities of the EU, for example EMA's contribution to the fight against antimicrobial resistance or the Agency's interactions with Health Technology Assessment (HTA) bodies.
- **Category 3**, includes the lowest priority activities: the development of the European Medicines Web Portal, a new publicly available online information source on all medicines marketed in the EU; EMA's contribution to the e-submission project; the development of a transparency roadmap; participation in the benchmarking of medicines regulatory authorities in the EU as of 2018.

Impact of disruption on business continuity and public health

EMA's business continuity plan is mostly consistent with areas that are most impacted according to our analysis as summarised below. As highlighted in Table 3, according to our analysis, two areas of activity have the greatest risk of disruption due to the relocation of EMA, these include:

- EMA's evaluation of applications for MA,
- Post-marketing activities, namely pharmacovigilance.

Any disruption to these activities are likely to have direct implications for patients unless they are adequately prioritised and contingency staff (seconded national experts) are provided where necessary.

Failure to ensure adequate staff in these areas could mean that EMA is not able to abide by the legal procedural timelines – or "timeouts" are used inappropriately. This could lead to delays in patient access to new life-saving therapies and a potential dysfunctioning in the coordination of pharmacovigilance activity.

This would mean that when adverse effects and toxicity appear, such information may not be analysed and communicated effectively across the European network, and this could lead to a slower reaction to monitoring, detection and assessment of adverse drug reaction (ADRs) across Member States.

Disruption is some activities could have knock-on effect on other activities. This is the case, for example, for the paediatric department, because of the role of the paediatric investigation plan (PIP) in MA, and disruption of which may impact the MA process. Additionally, the workload in some departments may increase as a result of Brexit, such as MA variations or a requirement for new site inspections, which also has implications on business continuity.

IT capacity is very important, and this is a potentially fragile part of the Agency because a lot of activities are dependent on these resources. However, the risk is related to transition management rather than the relocation destination.

A significant concern is that activities that are important in the medium term may be neglected. The result of this would be that Europe "falls behind" the rest of the world in terms of regulatory science; there is especially concern about falling behind Japan and the US. This could have a particular impact on investments into the European market.

Table 3: Ranking of activities by their level of risk of disruption & impact on business continuity and public health

	Risk of disruption and impact on business continuity	Impact on public health
Evaluating applications for marketing authorisation	Loss of expertise and procedural experience in this area would lead to a significant level of disruption to EMA's ability to coordinate the CHMP and could jeopardise the entire MA process	This would result in a direct impact on patients' ability to have timely access to new treatments
Monitoring the safety of medicines across their lifecycle	Risk of disruption in this area is high, due to management of the IT systems and the high volume of safety signals across the network	This disruption may impact critical safety functions of the EMA and lead to delays in the identification, management and communication of product safety issues
Facilitating the development and access to medicines	There is a moderate risk of disruption in this sector. Some areas directly link to the longer-term marketing authorisation process. In other cases, the damage is on longer-term EU competitiveness	This would not result in direct impact on patients in the short-term. However, this could have a knock on effect on other parts of the regulatory process and on long-term incentives to innovate
Compliance & development of standards	This area has a lower risk of disruption as the activities require fewer EMA resources. However, some scientific and regulatory expertise, such as the coordination of inspections or the involvement in ICH are an essential support function	This would have less of an immediate effect on the public compared to the previous activities
Disseminating information	Whilst these activities are completely dependent on EMA staff, this segment is based on reports already generated through other EMA activities, and has the least potential to cause problems with business discontinuity	Many stakeholders would regard the dissemination of information very useful in driving standards and meeting regulatory requirements, but is not critical in terms of public health

High impact on public health | Medium impact on public health | Low impact on public health

Source: CRA analysis

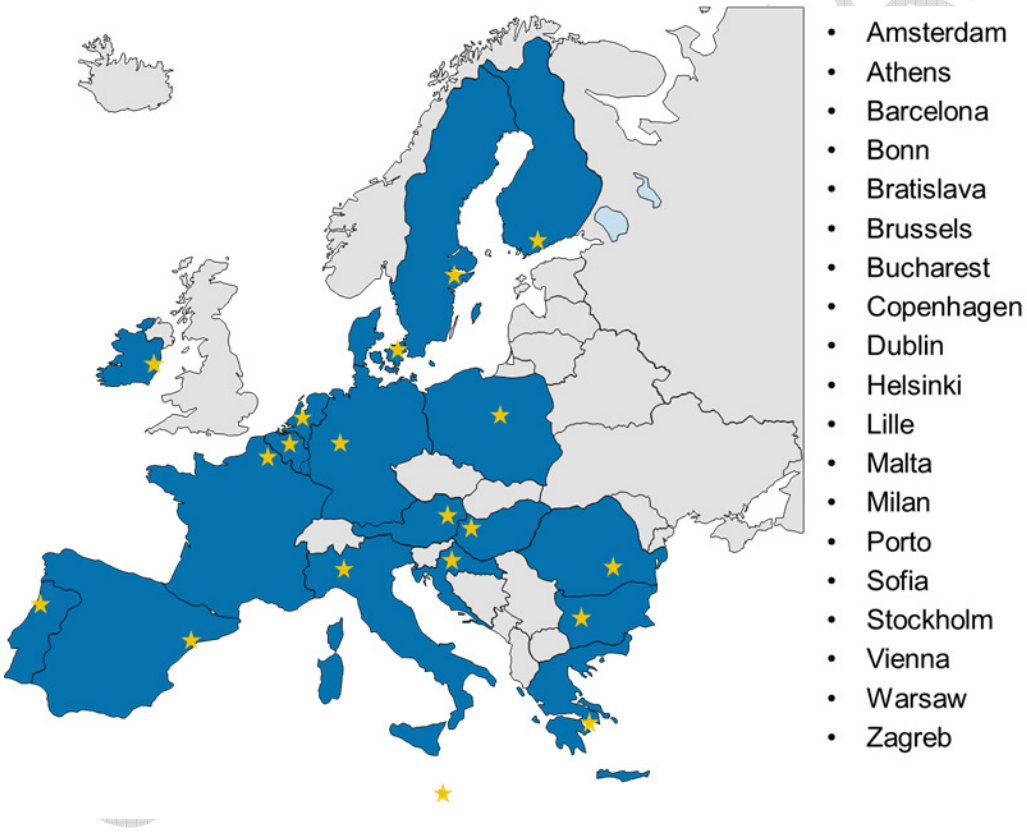
4. Assessment of locations

The second step is a qualitative assessment of the 19 official bids submitted for hosting the EMA.[35] To do this we use the EU criteria and set out how this criteria can be turned into a series of metrics (taking into account the industry priorities in terms of business continuity and corresponding impact on public health). We then apply this template to the different bids for the relocation of EMA.

4.1. European Commission criteria

By the deadline on the 31 July, 2017, a total of 19 cities had been proposed to host the Agency (see Figure 6).

Figure 6: Official offers to host the European Medicines Agency



Source: European Commission

We start off our assessment by looking at the official criteria set out by the European Commission for the relocation of the European Medicines Agency and the European Banking Agency. These are based on criteria for the decision on the location of seat of an

35 European Council of the European Union. Offers to host the European Medicines Agency (EMA). Available at: http://www.consilium.europa.eu/en/policies/relocation-uk-based-agencies/ema/

agency set out in point 6 of the Joint Statement and Common Approach on Decentralised Agencies.[36] These criteria are set out in Table 4.

Table 4: Criteria set by the European Commission

Criterion	Description
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	In particular the availability of appropriate office premises in time for the Agency to be able to take up its functions. This should include the necessary logistics and sufficient space for offices, meeting rooms and off-site archiving, high-performing telecommunication and data storage networks.
The accessibility of the location	The availability, frequency and duration of flight connections from the capitals of all EU Member States to the airports close to the location, as well as the quality and quantity of accommodation facilities.
The existence of adequate education facilities for the children of agency staff	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 future capacity.
Appropriate access to the labour market, social security and medical care for both children and spouses	The capacity to meet the needs of the children and spouses of the current as well as future staff for social security and medical care as well as the availability to offer job opportunities.
Business continuity to ensure continued functionality at the existing high level	This relates to the time frame required to fulfil the four criteria above. 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.
Geographical spread of the agencies' seats	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.

Source: European Commission[37]

36 Council of the European Union (2017). Procedure leading up to a decision on the relocation of the European Medicines Agency and the European Banking Authority in the context of the UK's withdrawal from the Union, 22/06/2017, http://www.consilium.europa.eu/en/press/press-releases/2017/06/22-euco-agencies-relocation/

37 Council of the European Union (2017) Procedure leading up to a decision on the relocation of the European Medicines Agency and the European Banking Authority in the context of the UK's withdrawal from the Union, 22/06/2017, http://www.consilium.europa.eu/en/press/press-releases/2017/06/22-euco-agencies-relocation/

These criteria provide a useful framework to consider the assessment of bids. However, as the aim of this report is to provide an industry perspective, it was felt that additional indicators should be added to complement the above EC criteria.

4.2. Augmenting the European Commission criteria

The aim of this analysis is assess each country in terms of how it meets the European Commission's (EC's) requirements, but also taking into account the industry's priorities for business continuity. We have aligned metrics to each of the criteria. Some of these have already been articulated by the EC, while others are industry proposed indicators.

We have developed metrics reflecting our understanding of the goal of criteria, particularly the need to retain EMA's staff. According to experts, retaining 70% of staff would be good in terms of continuing normal activities and this needs to be prioritised. This has implications for the metrics, for example in terms of adequate education facilities.

- In addition to the number of school places required for the children of EMA staff, it is important to consider the **capacity of schools to meet EMA's demands** (e.g. number of European/International schools, total school capacity and availability of places), and how that could affect the attractiveness of the location.
- In terms of **labour market, social security and medical care**, the future location needs to be able to meet the demands for spouses and other family members. In this respect, standards of living and quality of life are measured using standard metrics from European Commission Eurostat Quality of Life index[38]; as well as a standard measure of healthcare access and quality, based on the Lancet's "Healthcare Access and Quality Index"[39], which are both important factors in assessing the attractiveness of the location.

Others metrics have come from the interviews with industry regulatory experts, including their experience in relocating of activities. For example, given their experience of the EMA process, they noted the following considerations:

- **Accessibility of the Agency.** The ability to easily access the location of EMA is vital for the regular meetings with the external European network of experts as set out in the criteria. However, the ability to make day trips is important for participation in key meetings. Thus, both day trip connectivity and the ability to get the last flight out after the previous business day is important in order to maximise participation in expert meetings.
- **Adequacy of office logistics.** Given that the possibility of a transition period is unknown, the location needs to be ready to host EMA operationally as of March

38 Eurostat website: Quality of Life (QoL) indicators for the EU. The "overall experience of life" refers to the personal perception of quality of life (i.e. life satisfaction, affects, meaning of life). The data presented here come from several sources from within the European Statistical System (ESS), in particular SILC (statistics on income and living conditions), LFS (labour force survey), EHIS (European Health Interview Survey), and administrative sources. Additional information at http://ec.europa.eu/eurostat/web/gdp-and-beyond/quality-of-life/data:

39 Oladimeji, O., & Healthcare Access and Quality Collaborators, G. B. D. (2017). Healthcare access and quality index based on mortality from causes amenable to personal health care in 195 countries and territories, 1990-2015: a novel analysis from the Global Burden of Disease Study 2015. Accessible at http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)30818-8/abstract

2019. This means transfer will need to occur much earlier than this. In order to make the relocation as smooth as possible, the building needs to be ready. Therefore, in cases where the premises are new and only planned to be ready by March 2019, this adds considerable risk to business continuity.

However, we have also drawn on the insights from Step 1; for each criterion there are additional considerations to ensure business continuity and operational efficiency of the Agency:

- **The ability to hire skilled staff aware of the EU regulatory requirements.** If the relocation does result in a loss of key staff, the ability to employ or second staff to these positions is important for business continuity.
  - One option would be to draw in staff from the local host agency or from the industry. When EMA moved to London in 1995, secondment and drawing staff from other agencies and companies were all important.[40] Staff from the NCA would be aware of the procedures for MA applications. Therefore, depending on the size and spare capacity of the NCA, it could be possible for the host to provide secondments to the EMA during the time of the transition.
  - The size of the life science industry may also play a role in this. Regulatory pharmacists from industry could potentially be used across EMA departments, and ex-inspectors could fill many compliance roles within the Agency. That being said, there are legal boundaries surrounding hiring staff directly from industry, as they are restricted from working on submissions from their previous employers for a period of time.

We have therefore included the NCA and the number of pharmaceutical headquarters or facilities in our assessment. This is secondary to retaining EMA's staff but still important in ensuring business continuity. It also varies by activity, with some countries having more manufacturing sites (e.g. Ireland), relevant for EMA's role in coordinating inspections, while others have more scientific and regulatory experts (e.g. France, Germany), and are therefore more able to replace staff involved in activities associated to MAs.

The result is a set of metrics that reflect EC criteria and the priorities of business continuity (see Table 5). This reflects the importance of the location to support staff retention and the ability to backfill any staff losses if there is a gap during the transition period.

Table 5: List of indicators used for the bid analysis

European Commission criteria	Linkages to continuity of EMA's activities	Indicators
Adequate office logistics	Sufficient capacity of office space that meets all of the requirements for EMA to carry out its activities (e.g. expert meetings and IT/systems management)	• Location ready to use at the time of Brexit • Meeting room facilities • Records management and archiving • IT capacity and data servers • Security infrastructure

40 Interview with regulatory expert.

Accessibility of the location	Ability of EMA to access external expertise across Europe for regular meetings. If experts are unable to travel efficiently, this could lead to substantial delays in activities	• Direct daily travel connections and proximity to other EU capitals • Feasibility of day trips from other EU cities • Feasibility of getting the last flight out after the business day • Resiliency of transport connections • Sufficient hotel capacity
Adequate education facilities	Suitable education facilities for children of EMA staff in order to support staff retention	• Number of international or European schools • Capacity of schooling system i.e. availability of places to meet EMA requirements
Labour market, social security and medical care	The attractiveness of the location for EMA staff and their families from a quality of life perspective in order to support staff retention	• Employment opportunities for spouses • Availability and quality of housing • Healthcare Access and Quality (The Lancet Healthcare Access and Quality Index index) • Size of international population • Overall life satisfaction (Eurostat QoL index)
Business continuity	Ensuring the location offers minimal disruption to EMA's activities during the transition period Potential for new location to facilitate staff retention, and as a backup, provide a talent base to backfill any staff shortages after relocating	• Support provided by host government during the transition period to guarantee the daily operations of EMA • Size, capacity and location of national competent authority • Skill set from local life sciences industry relevant to EMA's activities

Source: CRA analysis

4.3. Analysis of bid assessment

Using the indicators listed in Table 5, we have undertaken an assessment of the official bids submitted for hosting the EMA against the EC's criteria. The aim of this analysis is not to make a specific recommendation of which city is best suited to host the agency, but to provide an overall assessment of the suitability of each bid. We therefore focus on identifying whether some of the conditions of each location would increase the risk of disruption and jeopardise business continuity, for example, by putting at risk EMA's ability to retain its current staff or attract new employees with relevant expertise. The results of our analysis is presented in Table 6 below. We have adopted a traffic light system where green dots indicate that the bid meets or exceeds the criteria; amber dots indicate that the criteria is met but with some limitations, and red dots indicated that the bid does not meet the criteria and this could represent a risk to business continuity.

A more detailed qualitative assessment of each of the official bids can be found in appendix I. This contains some of the details how each of the criteria are met as well as the limitations of each bid in meeting these criteria.

Table 6: Qualitative assessment of bids by key indicators

		Amsterdam Netherlands	Athens Greece	Barcelona Spain	Bonn Germany	Bratislava Slovakia	Bucharest Romania	Brussels Belgium	Copenhagen Denmark	Dublin Ireland
Adequate office logistics	Location ready to use at the time of Brexit	🟠	🟢	🟢	🟠	🟢	🟢	🟢	🟢	🟠
	Meeting room facilities	🟢	🟢	🟢	🟢	🟠	🟢	🟢	🟢	🟢
	Records management and archiving	🟢	🟢	🟢	🟢	🟢	🟢	🟢	🟢	🟢
	IT capacity and data servers	🟢	🟢	🟢	🟢	🟢	🟢	🟢	🟢	🟢
	Security infrastructure	🟢	🟢	🟢	🟢	🟢	🟢	🟢	🟢	🟢
Accessibility of the location	Direct daily travel connections to most EU capitals	🟢	🟠	🟢	🟠	🟠	🟠	🟢	🟢	🟢
	Direct international flights to US or Japan	🟢	🟠	🟠	🟠	🟠	🔴	🟠	🟢	🟢
	Feasibility of day trips from other EU cities	🟢	🔴	🟢	🟠	🟠	🔴	🟢	🟢	🟠
	Feasibility of getting the last flight out	🟢	🟠	🟢	🟠	🟠	🔴	🟢	🟢	🟢
	Resiliency of transport connections	🟢	🔴	🟢	🟢	🟢	🔴	🟢	🟢	🟠
	Sufficient hotel capacity	🟢	🟢	🟢	🟢	🟢	🟢	🟢	🟢	🟢
Adequate education facilities	Number of international or European schools	🟢	🟢	🟢	🟢	🟠	🟢	🟢	🟢	🟢
	Capacity of school to meet EMA requirements	🟢	🟢	🟢	🟢	🟠	🟠	🟢	🟢	🟠
Labour market, social security and medical care	Employment opportunities for spouses	🟢	🟠	🟢	🟢	🟠	🔴	🟢	🟢	🟢
	Availability and quality of housing	🟠	🟠	🟠	🟢	🟢	🟢	🟢	🟢	🟢
	Quality of healthcare (Lancet healthcare access and quality index, green: >85%, red: <60%)	🟢	🟢	🟢	🟢	🟠	🟠	🟢	🟢	🟢
	Size of international population	🟢	🟠	🟢	🟢	🟠	🟠	🟢	🟢	🟢
	Overall life satisfaction (Eurostat index, green: >75%, red: <60%)	🟢	🟠	🟠	🟠	🟠	🟠	🟢	🟢	🟠
Business continuity	Support provided by host government	🟢	🟠	🟢	🟢	🟠	🟢	🟢	🟢	🟢
	Size, capacity and location of NCA	🟢	🟠	🟠	🟢	🟠	🔴	🟠	🟢	🟠
	Skill set from local life sciences industry	🟢	🟠	🟢	🟢	🟠	🔴	🟢	🟢	🟢

🟢 Meets and exceeds the criteria 🟠 Meets the criteria but with some limitations 🔴 Does not meet the criteria

		Helsinki Finland	Lille France	Malta	Milan Italy	Porto Portugal	Sofia Bulgaria	Stockholm Sweden	Vienna Austria	Warsaw Poland	Zagreb Croatia
Adequate office logistics	Location ready to use at the time of Brexit	🟠	🟢	🟢	🟢	🟢	🟢	🟠	🟢	🟠	🟠
	Meeting room facilities	🟢	🟢	🟠	🟢	🟠	🟠	🟢	🟠	🟢	🟢
	Records management and archiving	🟢	🟢	🟠	🟢	🟠	🟠	🟢	🟢	🟢	🟢
	IT capacity and data servers	🟢	🟢	🟠	🟢	🟠	🟠	🟢	🟢	🟢	🟢
	Security infrastructure	🟢	🟢	🟠	🟢	🟠	🟠	🟢	🟢	🟢	🟢
Accessibility of the location	Direct daily travel connections to most EU capitals	🟠	🟠	🟠	🟢	🟠	🔴	🟢	🟢	🟢	🔴
	Direct international flights to US or Japan	🟠	🟠	🔴	🟠	🔴	🔴	🟢	🟢	🟠	🔴
	Feasibility of day trips from other EU cities	🟠	🟠	🔴	🟠	🔴	🔴	🟠	🟢	🟢	🔴
	Feasibility of getting the last flight out	🟠	🟠	🟠	🟠	🔴	🔴	🟠	🟠	🟢	🔴
	Resiliency of transport connections	🟠	🟢	🔴	🟢	🔴	🔴	🟢	🟢	🟢	🔴
	Sufficient hotel capacity	🟢	🟢	🟠	🟢	🟢	🟢	🟢	🟢	🟠	🟢
Adequate education facilities	Number of international or European schools	🟢	🔴	🟠	🟢	🟢	🟢	🟢	🟢	🟢	🟠
	Availability of places to meet EMA requirements	🟠	🔴	🟠	🟢	🟢	🟢	🟢	🟢	🟠	🟠
Labour market, social security and medical care	Employment opportunities for spouses	🟢	🟠	🟠	🟢	🟠	🔴	🟢	🟢	🟠	🟠
	Availability and quality of housing	🟢	🟠	🟢	🟢	🟢	🔴	🟠	🟢	🟠	🟠
	Quality of healthcare (Lancet healthcare access and quality index, green: >85%, red: <60%)	🟢	🟢	🟢	🟢	🟢	🟠	🟢	🟢	🟠	🟠
	Size of international population	🟢	🟠	🟢	🟠	🔴	🔴	🟢	🟢	🟠	🟠
	Overall life satisfaction (Eurostat index, green: >75%, red: <60%)	🟢	🟠	🟠	🟠	🟠	🔴	🟢	🟢	🟠	🟠
Business continuity	Support provided by host government	🟢	🟢	🟢	🟠	🟢	🟠	🟢	🟢	🟢	🔴
	Size, capacity and location of NCA	🟠	🟢	🔴	🟠	🟠	🔴	🟢	🟠	🟠	🔴
	Skill set from local life sciences industry	🟠	🟢	🔴	🟢	🟠	🔴	🟢	🟢	🟠	🔴

🟢 Meets and exceeds the criteria 🟠 Meets the criteria but with some limitations 🔴 Does not meet the criteria

Appendix I: Qualitative assessment from the official bids submitted for hosting the EMA

AMSTERDAM

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	The Dutch government is offering a brand new office building as the new headquarters and the Central Government Real Estate Agency (CGREA) will collaborate with EMA to provide customised building solutions to ensure the space fulfils the Agency's specific requirements.	The development timeline aims to deliver the conference centre, as well as some of the workplaces, by April 1st 2019. However some of the remaining office floors would not be ready for a few months after. The Dutch government is offering a free temporary location for remaining staff, however this may impact stability during the transition period.
Accessibility of the location	The proposed office space is less than 10 minutes from Amsterdam Airport, with direct connections to all EU capital cities and a vast number of international destinations (including multiple US destinations). As such, Amsterdam has very good day trip feasibility to a vast number of EU capitals. There is potential for EMA staff to commute from London to Amsterdam, given the close proximity and over 50 flights a day serving London's airports. Amsterdam is within close proximity to Rotterdam and Brussels airports and there are high-speed rail connections to other cities such as Brussels, Paris and Frankfurt. Approximately 29,150 rooms are located in the city of Amsterdam, with a large selection in the 3- and 4-star range.	None
Adequate education facilities	There are over 22 International schools a commutable distance from the proposed site of the headquarters with sufficient capacity for EMA staff. There are also two European schools, which will be expanding capacity should the EMA relocate to Amsterdam, and a number of nurseries close by.	None
Labour market, social security and medical care	Amsterdam is one of Europe's most cosmopolitan and international cities has a long-standing tradition in hosting expats, with a vibrant job market. Amsterdam has a high quality of life with overall life satisfaction at 78% (Eurostat index) and high quality of healthcare at 90% (Lancet index).	Relatively high cost of living relative to some member states, primarily due to higher house prices and the rental market.
Business continuity	The government has provided a clear relocation schedule to provide transitional support to staff and activities of the Agency. Over the coming years the Netherlands will strengthen the regulatory capacity of the Dutch Medicines Evaluation Board and invest in an in-depth training programme for developing expertise and assessment capacity.	Temporary workspace for some staff could have implications for the operational efficiencies during the transition period.

ATHENS

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	Athens offers an established building with excess capacity to meet the EMA's requirements. Final building refurbishments are not expected to exceed 6 months from the date of official decision on the relocation of the Agency, allowing for an extended period of time for the transition prior to Brexit.	The bid does not provide specifications of meeting room allocations to establish whether there will be sufficient capacity for EMA activities.
Accessibility of the location	Athens has over 14,000 hotel rooms spread across 130 4 and 5 star hotels, allowing for plenty of availability for experts to stay.	Athens is relatively more remote geographically compared to other EU capitals. Air travel is the only way to reach other cities, and day trip feasibility is limited to nearby capitals such as Rome or Larnaca. There is seasonal differences in flight availability; in winter months direct flights are not available to 13 EU capitals. There are no direct flights to international locations such as Japan or Washington DC or other US cities (except NYC and Philadelphia).
Adequate education facilities	There are a number of schooling options to choose from, including 20 International schools and 10 European schools across Athens offering teaching in 7 different European languages. This provides sufficient capacity for the children of EMA staff.	There are only a limited number of pre-schools and nurseries close to the proposed location of the agency.
Labour market, social security and medical care	Greece has a moderate level of overall life satisfaction at 62% (Eurostat index) and a high quality of healthcare rating of 85% (Lancet index). As a top tourist destination there is local proficiency in many European languages.	There are more limited availability of international companies present in Greece relative to other EU countries. Athens has few international organisation and a high unemployment rate of 22% and the lowest employment rate in the EU which may limit employment opportunity and growth opportunities (i.e. professional development opportunities and access to professional social networks) for spouses and family.
Business continuity	The Greek government will establish a liaison office which will provide relocation-related services to EMA staff. This office will also be responsible for providing specialised services to spouses and partners regarding job-seeking.	Due to the small size of the NCA and importance of other policy priorities there is limited ability for direct support to be given to EMA through potential secondment opportunities. In terms of attracting future staff, Athens is less internationally connected to research and scientific community in the relevant fields

BARCELONA

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	Barcelona has a ready-to-use building (the Torre Glories), which meets and exceeds all requirements regarding building installations and security. A Steering Group will be formed by key stakeholders to ensure functionality and that the building meets the needs of EMA. Barcelona receives thousands of conferences every year and hosted 1,974 meetings in 2016 alone.	None
Accessibility of the location	The building is 25 minutes away from the airport and Barcelona airport has excellent flight connection to other European destinations making day-return trip to some locations in Europe possible. International connections are a little more limited (no direct flights to Tokyo) but Barcelona has direct flights to some major US cities such as NYC, Los Angeles, Miami, Philadelphia, and Chicago. Barcelona has sufficient hotel capacity for visitors, including a total of 218 high-end four and five star hotels, offering a total of 51,060 beds.	Barcelona can only connect to other EU capitals through air travel, it is connected to Paris and Brussels by train - though length of journey makes this option less feasible. Day trip feasibility is only viable for ten other EU capitals.
Adequate education facilities	There are 18 International schools that teach a foreign curriculum and conduct lessons in a variety of languages. There are also 23 multi-lingual schools that follows local curriculum in 7 different languages.	None
Labour market, social security and medical care	Spain has a moderate-high level of overall life satisfaction at 69% (Eurostat index) and a very high quality of healthcare rating of 90% (Lancet index). Catalonia (where Barcelona is located) is the region with the fifth highest number of jobs in high-tech industries in Europe, and seventh highest number of workers in science and technology.	None
Business continuity	The national competent authority (AEMPS) will strengthen its staffing structure and will be increasing the workforce by 60 people by 2019. Spain is second in Europe in input to the European network of experts for EMA. The Spanish Business Continuity Plan will have three key elements: talent retention; daily operations and infrastructure. The strategy aims to ensure the retention of talent by providing existing Agency staff with all the tools, information and support necessary for a smooth transfer experience, easing the process of moving through a series of landing services. €2.8 million initially committed to establish a sufficient talent pool and develop the necessary measures to ensure the continuity of EMA's work.	While the government has explained that AEMPS may also assign temporary staff (for example, in the weeks of the transfer) or longer-term temporary staff (between 1 and 6 months) to carry out or support activities for EMA, the location of the host authority is in Madrid so could have logistical challenges.

BONN

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	The German government proposes two new building options, both in a central location in Bonn's Bundesviertel district. Two existing building options are also available for more immediate use during the transition period between Brexit and the new building completion, which is set for 2020.	Two phases of relocation are required, a transitional Bonn location at the time of Brexit, followed by a new building location from 2020. This may impact stability during the transition period.
Accessibility of the location	Bonn is well-connected to other EU capitals due to its location within an hour's drive of 2 international airports. There are 2 internationally-connected train stations nearby that allow accessibility to at least 2 EU capitals within a 4-hour train journey.	The airport offering the most international connections (DUS) is more than an hour's drive from the proposed location.
Adequate education facilities	City of Bonn is prepared to set up a temporary day care for as many as 80 children until EMA can establish its own building-based day care center.	While there is availability in local schools, there is little information on availability of places in International and European schools to support the needs of EMA staff.
Labour market, social security and medical care	Germany has a high quality of life with overall life satisfaction at 73% (Eurostat index) and a high quality of healthcare rating of 86% (Lancet Index). Bonn has a very stable and attractive job market and there are a range of international companies headquartered locally and in nearby cities.	Whilst quality of life is deemed high in Bonn, the smaller size of the city make it less attractive to international expats compared to other German cities.
Business continuity	Bonn is prepared to leverage expert support from well-established organizations such as the BMG, BfArM, and BImA to ensure a smooth transition. The Federal Institute for Drugs and Medical Devices and the Paul Ehrlich Institute are large and well-established competent authorities who will provide technical and HR support to the EMA during the transition. The Federal Ministry of Health is prepared to form a dedicated project team to handle all logistics of relocation and two innovative migration scenarios have been developed for the EMA's IT relocation.	Compared to other country offers, there is limited support from the government on staff and family relocation assistance.

BRATISLAVA

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	New real estate development under construction is expected to be completed by the end of 2018 to meet all of EMA's specifications three months ahead of the proposed Brexit date.	No specific details provided on whether meeting room capacity will meet the demands of EMA's activities.
Accessibility of the location	Bratislava is situated within driving distance from Bratislava, Budapest and Prague, and is also close to Vienna airport, offering an alternative route for travel. Vienna airport is used as the primary airport for the region which has excellent connectivity with direct flights to all EU capitals, with two thirds of cities reachable within 2 hours. It is feasible to do day trips to Vienna from 20 of Europe's capitals. The hotel requirements for EMA visitors make up just 2% of annual hotel capacity in Bratislava. Additionally Vienna can be used as an alternative option for hotels and conferences.	Although Vienna is used as the primary transport hub, travelling from Vienna airport has a longer commute to the EMA location. The connection between Bratislava city centre and Vienna airport is complicated and not always an effective way to reach the city. When flying directly to Bratislava, the majority of flights are with low-cost airlines.
Adequate education facilities	The proposed site is just a few minutes' drive from 3 top international schools in Bratislava (incl. kindergartens, primary and secondary schools) and there is an international nursery is within the business park. There are also many options for expatriate children to attend bilingual secondary education with programs in English, German, French, Spanish, Russian, Italian and Bulgarian.	Limited information on availability of places in local international schools, with fewer numbers compared to other locations.
Labour market, social security and medical care	Slovakia has a moderate-high quality of life with overall life satisfaction at 70% (Eurostat index) and moderate quality of healthcare rating of 79% (Lancet index). In 2017 the central labour office registered about 3,000 available job positions for positions for English speakers, about 600 for German speakers and up to 100 French speaking positions.	While Bratislava also offers a much more affordable living environment relative to other EU cities, the average median income in Slovakia is much lower compared to other EU economies making it less attractive to international expats.
Business continuity	Slovakia plans to make substantial investments into the State Institute for Drug Control (SIDC). Additional personnel and technical equipment will increase SIDC's capacity and expertise. The Slovak education system and labour market provide sufficient amount of highly-qualified experts who could be temporarily hired by EMA during the transition.	The Life Sciences industry and talent base is smaller than some other EU countries.

BRUSSELS

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	Belgium proposes an office building located right in the European Quarter in Brussels, which allows synergies with the nearby EU institutions. The building meets and exceed all the EMA requirements. This is currently under construction and will be delivered by mid-November 2018, enabling the European Medicines Agency to be fully operational by April 2019.	The building will fully operational by April 2019 - just on time for the move. This may not provide sufficient transition period to allow the progressive move of EMA staff.
Accessibility of the location	Brussels Airport is easily accessible via a direct train connection in 20 mins, making day trip connectivity to most cities in Europe feasible. It offers good connection to most European destinations. Brussels South Charleroi Airport and Liege airport also has daily connections to all over Europe. Brussels-Midi train station offer high-speed train connections to 19 cities, including Paris, London, Amsterdam, Lille, Cologne and Frankfurt within 3-4 hour train ride.	International flights are limited from Brussels but good international connections are available from Paris CDG or Amsterdam Schiphol.
Adequate education facilities	Given the presence of the EU institutions, Brussels has a large range of international schools. More than a third of European Schools are located in Belgium (5 European schools in Brussels) and a fifth European School for 2,500 pupils will open in the Brussels Greater Area in the near future. British and American curricula can be found alongside international and European curricula at various schools.	None
Labour market, social security and medical care	The Brussels region is home to 180 nationalities and more than 55% of residents were not born Belgian. The European and international institutions have turned Brussels and international city with many job opportunities for expats - there are over 20 Organisations of the European Union present in Brussels and 42 Intergovernmental organisations such as NATO and Eurocontrol. There are 121,000 Jobs generated by international institutions in Brussels (not including private-sector companies) - 81,000 directly and 40,000 indirectly. Overall life satisfaction is 76% (Eurostat index) and there is a high quality of healthcare rating of 88% (Lancet index). English is fluently spoken by most Belgians for whom multilingualism is a given.	None
Business continuity	The Belgian government has the capacity and the commitment to enhance the FAMPH (Belgian Medicines agency) capabilities and resources for a smooth move towards Belgium within a short timeframe and with respect for business continuity.	Belgium has a relatively small medicines agency making opportunity for secondments more limited.

BUCHAREST

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	Romania has offered a new building that will complete construction by the end of 2017 and will meet all the resource requirements of the EMA. The building has a flexible layout and can accommodate multiple tenant requirements, on site facilities, and activities.	None
Accessibility of the location	Bucharest has almost 10,000 hotel rooms across its 3-5 star hotels, with another 150 in development over the coming years.	Bucharest has direct flights available to only 50% of EU capitals and it is only possible to do day trips from 3 nearby cities. The direct train line between the airport and the new office location is not yet completed and currently under construction which can make reaching the airport difficult. Alternative transport modes (e.g. international trains) to other EU destinations to other EU capitals is limited.
Adequate education facilities	Bucharest has 30 international schools that provide teaching in languages other than Romanian. Nurseries are also readily available.	None
Labour market, social security and medical care	Romania has a moderate-high quality of life with overall life satisfaction at 71% and moderate quality of healthcare rating of 74% (Lancet index). The cost of living in Romania – especially in Bucharest – is approximately 50% lower when compared to other EU major cities. Foreign nationals are mostly employed in the Business Services Sector, which employ in a variety of languages.	There are few international companies present and higher-paying jobs are scarce in comparison to other EU capitals, which would likely impact job options for spouses. Less obvious, but equally important, are aspects such as gender equality and access to growth opportunities', professional development opportunities) which are low in Bucharest relative to other European cities
Business continuity	Romania has created a partnership agreement with a local university to provide EMA with 1900 skilled people (300 of which are from the National Agency for Medicines and Medical Devices) to cope with a possible 25% EMA staff shortage. The authorities will create a dedicated task force to assist with all aspects of family relocation and a confidential government financial contribution has also been submitted to EMA.	The Life Sciences industry and talent base is smaller than other EU countries.

COPENHAGEN

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	New building that meets all of EMA's requirements and will be fully operational in March 2019. The building, divided into 4 towers which could help divide staff according to their appropriate level of clearance, is situated close to the airport and train stations. The Danish Government has reserved this office space and can provide an additional off-site archive facility for EMA.	The proposed timeline has EMA fully operational in Copenhagen by March 2019, and as the building is new there is no option to gradually transition staff to Copenhagen prior to the final relocation date.
Accessibility of the location	Copenhagen is well-connected to other EU capitals by plane, having the largest airport hub in Northern Europe. It is possible to do day trips to Copenhagen from 50% of EU capitals, all taking less than 2 hour flight time. There are direct connections to other international locations such as Tokyo and Washington DC.	Copenhagen has more limited flight connections to Eastern European countries. There is only one airport available as an international transport hub for travelling to other EU destinations.
Adequate education facilities	Copenhagen offers 14 international schools in addition to a European School, which is free of charge.	Copenhagen has a lower number of nurseries, pre-schools, and primary schools located in the city.
Labour market, social security and medical care	Denmark ranks consistently high on the quality of life index, including having one of the highest overall life satisfactions (80%), job satisfaction (81%), and satisfaction with living environment (84%) according to Eurostat. Quality and access to healthcare is rated highly at 86% (Lancet index) The Danish labour market is highly accessible to expats. There are on average five hundred job vacancies in English in the Copenhagen area alone. Copenhagen is experienced in hosting international organizations, including the European Environment Agency and 11 UN agencies, making Copenhagen the sixth largest UN hub in the world.	None
Business continuity	The Danish Government has created a clear transition plan to cover the three main issues of completing the new building, relocating EMA staff, and ensuring business continuity. The timeline also establishes milestones addressing the recruitment of new staff and the migration of IT infrastructure and services. Copenhagen has strong cluster of companies operating in the biotech, pharma and medical devices industries, creating the necessary environment for an agency such as EMA to attract and retain qualified staff from across Europe.	Outside of a targeted talent attraction set by the government, there is limited details on how the Danish national competent authority could provide specific support to EMA through the transition period.

DUBLIN

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	The Irish Government has provided three new options for the EMA, which fully deliver on the technical specifications. One location is at walking distance from the airport and the other two locations within 20 minute drive. The National Archives of Ireland will assist the EMA in identifying the best solutions for record management.	Two of the locations have a completion date after Brexit (March 2019), meaning the agency would need to remain in London for a longer period, with no contingency plan if the agency is forced to move out of London by the date of Brexit. As the buildings are new, there is no option to gradually transition staff to Dublin prior to the final relocation date.
Accessibility of the location	Potential for EMA staff to commute from London to Dublin, given the close proximity and over 35 flights a day serving London's airports. Dublin has daily direct flights to almost all EU capitals and has one of the best international connections to the US with over 17 flights a day to major US destinations such as NYC, Washington, Boston and Los Angeles. There is hotel capacity to support experts visiting the Agency	Dublin is more geographically remote compared to other EU capitals which means it is only feasible to do day trips from two other EU cities. Air travel is the only way to connect to other EU destinations. Many flights to EU capitals are only with low-cost airlines.
Adequate education facilities	Dublin has 3 International schools and 1 European school close to the city centre. Dublin also offers two 'Eurocampus' schooling models based on the French system with all classes taught in French.	A lower number of international schools relative to other EU cities and little information on availability of places in International and European schools to support the needs of EMA staff.
Labour market, social security and medical care	Ireland has a high quality of life with overall life satisfaction at 74% (Eurostat index) and high quality of healthcare rated at 88% (Lancet index). Dublin is seen as a progressive, diverse and multicultural modern European city, and the living conditions similar to London, enabling a smoother transition. Dublin has a large international population and many high-skilled employment opportunities in international companies. English is an official languages and most commonly used.	None
Business continuity	The government has established a 'Transition Taskforce' and set a relocation timeline with interim milestones addressing issues such as recruitment, accommodation etc. Ireland's medicines regulator is set to scale up its resources and regulatory activities to work with EMA. Ireland has well established pharma manufacturing industry and local inspectors for EMA to fill gaps in compliance roles.	The transition timeline only takes into consideration moving into the one location that would be ready by March 2019, and provides no contingency plan for other options.

HELSINKI

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	The Finnish Government has identified four possible building options for EMA, with a primary recommendation for a building located in central Helsinki that fully delivers on EMA's needs. The ongoing construction project that will be completed by Q1 2019 and can still be tailored to EMA's specifications and the government will leverage expertise from the national competent authority (FIMEA) for construction.	Since the building is currently under construction, it is yet unclear if any changes that EMA desires to the building will be completed in the currently proposed timeline.
Accessibility of the location	The building is located about 1km from the railway station and 900m from the metro lines, providing walkable access to public transportation.	As a more remote capital, Helsinki only offers direct flights to two thirds of EU capitals, with day trip feasibility for experts only possible for 6 nearby cities. Air travel is the only way to connect to other EU destinations and there are limited flights to US destinations
Adequate education facilities	The wider Helsinki region offers 6 international schools, a European and British school, and several other types of schooling in a variety of European languages.	Selection of International, European, and British schools is more limited in the city.
Labour market, social security and medical care	Finland ranks consistently high on the quality of life index, including having one of the highest overall life satisfactions (80%), job satisfaction (81%), and satisfaction with living environment (84%) according to Eurostat. There is very high quality and access to healthcare, rated at 90% (Lancet index).	More expensive housing and rental market, which may present a financial constraint for some EMA staff. That being said, the City of Helsinki will make an agreement with a brokerage company that will help EMA staff and families to find suitable residential solutions in Helsinki.
Business continuity	Finland will offer a tailored package to spouses and families of the agency's employees to help them find new homes, schools, and other necessary facilities to support relocation. Finland would leverage the expertise of FIMEA to contribute to the search for new temporary and permanent staff to bridge the gap in expertise in the event of high turnover.	Pharma and life sciences-related universities and institutions are still being developed in Finland and currently there is only a small number of these universities readily available to attract new talent.

LILLE

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	France proposes to build a new, tailor-made building to meet the Agency's specific needs to be delivered in January 2019. The list of EMA specifications for the building was adopted. Lille is covered by super-fast fibre optic broadband, and will fit the "biotope" building with hardware to ensure access to this network.	None
Accessibility of the location	The building is a 5-minute walk from Lille-Flandres railway station and a 10-minute walk from Lille-Europe railway station, which are on high-speed lines with fast connections to London, Brussels, and Paris. These cities are located within a radius of 330 km of Lille.	Lille has a small international airport but with few European destinations. The nearest airport is Paris CDG or Brussels Zaventem (both over 55 min reach by high speed train), which limits accessibility to more remote capital cities in Europe and limits day-trip feasibility.
Adequate education facilities	France has a high-quality public schooling system and Lille has a large variety of state schools and private schools with international sections, some of which offer bilingual programme and the International Baccalaureate diploma. Five nurseries offer bilingual care and a 6th will be established at EMA itself.	Lille has limited availability of International schools. However a new European school is due to open in September 2019.
Labour market, social security and medical care	France has a moderate-high quality of life with overall life satisfaction at 71% (Eurostat index) and high quality of healthcare at 88% (Lancet index). London, Brussels, and Paris are located within commuting distance to Lille offering a range of international living options and adequate access to a large labour market for family members.	Despite having a vibrant domestic business sector, Lille has relatively few international organisations or international company headquarters, limiting access to carrier growth opportunities (i.e. professional development opportunities and access to professional social networks).
Business continuity	Lille has good access to internationally connected research and scientific community and a pool of top-level scientific experts at its disposal, France will be able to offer its support to EMA in its search for staff. France will increase the capabilities of its national agency for the safety of medicines and health products (ANSM), so that it can stand ready to manage future projects	The national medicines agency (ANSM) is located in Paris, an hour away from Lille meaning it can only offer limited day-to-day support during the transition in terms of staffing.

MALTA

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	The Government is offering a bespoke premises to host over 1,000 employees in a technology park close to the airport. The space is planned to be ready 6 months prior to April 2019. The Conference facilities are spread all over the Maltese islands and include 289 conference halls.	No specifications of office space provided in the bid to understand if it will meet the EMA requirements (e.g. appropriately sized meetings rooms, archive space, security infrastructure etc.)
Accessibility of the location	Malta has a number of hotels with good availability, however hotel openings can be quite seasonal.	Availability of flights is very seasonal, and in many cases there are only 1-2 flights per week. Eight EU capitals have no direct flights. Malta is more geographically remote compared to other EU capitals and it is only feasible to do day trips from Rome. There is only one airport available as an international transport hub for travelling to other EU destinations
Adequate education facilities	A high degree of multilingualism reflected in the educational system (English, French, German, Italian and Spanish) with a number of schools offering International and European oriented curricula and qualifications.	Limited information on availability of places in International schools or nurseries to support the needs of EMA staff.
Labour market, social security and medical care	Malta has a moderate-high quality of life with overall life satisfaction at 71% (Eurostat index) and high quality and access to healthcare at 85% (Lancet Index). In 2016 Malta was placed second in the Expat insider survey and performed well in all areas of expat life, primarily due to high standards of living, combined with low living costs. Malta has the lowest unemployment rate in the EU (4.2%).	Being a small-sized country, there are few international companies present in Malta, this may limit growth opportunities (i.e. professional development opportunities and access to professional social networks) for spouses and family.
Business continuity	The government is providing rent free premises for 15 years.	The government has not provided a relocation timeline or detailed any specific assistance it will provide during relocation. Malta has a small medicines authority of 49 people, meaning only limited support could be provided through the transition. The Life Sciences industry and talent base is smaller than other EU countries

MILAN

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	Milan has chosen a major landmark building for EMA that meets all the resource requirements of EMA with extended capacity. The building currently serves as the headquarters of the Regional Council, so high safety and security standards are already in place. The layout of the office space is extremely flexible and it will be adapted according to EMA's specific needs. A complete renovation project has already been drawn up and will be made available to EMA is the new headquarters is assigned to Italy.	Although the building currently meets all EMA needs, the office building is an older building last renovated in 2004 and it's unclear how further modernizations that EMA may desire would affect the construction timeline.
Accessibility of the location	Milan is well-connected to EU capitals by plane with direct flights to almost all EU capitals and day trips feasible for 50% of cities. The building is located in front of the city's main train station and Italy has an extensive train network that connects travellers to Rome or Bern in under 4 hours. A total of 58, 3, 4, or 5-star hotels are located within 10 minute walking distance (14,685 rooms, almost 48% of them within 1km of the Pirelli building).	The building is located far from the city's major international airport (>50km), which presents an inconvenience to visiting EMA experts.
Adequate education facilities	Milan offers a comprehensive network of 16 International schools that offer availability for 2,300 places. There are also 18 university-level institutions. A nursery/kindergarten for the children of EMA staff will be set up within the building as part of the adaptation works.	There are a limited number of European and British schools available in the area.
Labour market, social security and medical care	Italy has highly rated quality and access to healthcare at 89% (Lancet index). There are many employment opportunities with international companies in Milan.	Italy has moderate overall life satisfaction of 67% (Eurostat) for one of the EU's larger economies.
Business continuity	A clear transition plan has been established to offer workstations to EMA staff in advance of Brexit and dedicated support teams for relocating both EMA and family members. Italy has the second largest pharmaceutical industry in Europe in terms of production volumes, offering a wide talent base to backfill certain roles after relocating.	The national competent authority (AIFA) is located in Rome, meaning there is only potential for limited day-to-day support in terms of staffing during the transition period.

PORTO

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	The Portuguese government has identified three potential locations for the EMA - two of which are existing buildings and one that would be built post-relocation decision. All locations are scheduled to be completed by the scheduled Brexit date of March 2019.	No specifications of office space provided in the bid to understand if it will meet the EMA requirements (e.g. appropriately sized meetings rooms, archive space, security infrastructure ect.)
Accessibility of the location	All three locations are in the most cosmopolitan area of Porto, and thus are easily accessible by public transport. A frequent air-bridge connects Porto Airport to Lisbon (Humberto Delgado airport), where many international connections are available.	Availability of flights is very seasonal, and many EU capitals do not offer direct flights to Porto. Porto is more remote compared to other EU cities and there are no direct flights available from Porto to Tokyo or Washington DC.
Adequate education facilities	International schools in Porto have more than triple the capacity necessary for the children of the EMA staff. The Ministry of Education will establish a dedicated team for the EMA staff children's educational careers.	Little information on the number of school places available for each grade level.
Labour market, social security and medical care	Portugal has quality and access to healthcare rated at 85% (Lancet index), but a moderate quality of life with overall life satisfaction at 62% (Eurostat Index).	There are few international companies present in the Porto region, which means employment opportunities for spouses may be limited.
Business continuity	A dedicated "Welcome One-Stop-Shop" will be established on location in London in the months preceding the Agency's relocation, and will remain available in Porto in the 18 months following relocation. The government is planning to invest 4.8 million euros in INFARMED (the Portuguese national competent authority) over the coming years to strengthen its capabilities	Although INFARMED (the Portuguese national competent authority) has a staff size of over 300, it is located in Lisbon meaning it can only offer limited day-to-day support during the transition in terms of staffing.

SOFIA

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	The Bulgarian Government proposes a newly built office space to house the EMA headquarters. They are currently at the planning stage, but plan to be fully operational by no later than Jan 2019.	No specifications of office space provided in the bid to understand if it will meet the EMA requirements (e.g. appropriately sized meetings rooms, archive space, security infrastructure ect.) There are also no details of the technical specifications.
Accessibility of the location	The proposed location of EMA is less than 10 minutes from Sofia airport and from the City center. There are 12 000 hotel rooms at different price levels, 5 000 of which are located within 4km from the Agency's Headquarters.	Sofia only has direct flights to two thirds of all EU capitals, and due to the infrequency of flights it is only possible to make day trips from Vienna, Rome and Bucharest. Many flights to EU capitals are with low-cost airlines and there are no international connections to Japan or the USA.
Adequate education facilities	Sofia has a selection of 5 international schools serving children of varying grade levels. There are also German and French schools.	Limited information on availability of places in International schools to support the needs of EMA staff.
Labour market, social security and medical care	The EU law will apply accordingly to staff and members of their families so that they are granted adequate access to Bulgarian labour market and can benefit from the social security system in the country.	Bulgaria has reported one of the lowest overall life satisfaction in the EU (48%) and Satisfaction with the living environment (52%) is also well below the EU average of 73% (Eurostat index). Bulgaria has a moderate quality and access to healthcare rating of 71% (Lancet index), which is the lowest out of all bidding countries. There are few international companies present in Bulgaria, which would likely impact job options for spouses.
Business continuity	The government is providing rent free premises for the first year following relocation.	The government has not provided a relocation timeline or detailed any specific assistance it will provide during relocation. Bulgaria has a small medicines authority, meaning only limited support could be provided through the transition. Additionally there is a small biopharmaceutical presence, thus a more narrow talent base compared to other EU countries

STOCKHOLM

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	Two different building locations have been offered – a new building in Life City (Stockholm's Life Sciences cluster) or Stockholm's former Central Post Office building is an alternative option. Stockholm is considered to be a world-class IT city offering incredibly fast and reliable fibre-optic connections.	Life City is projected to be complete by Q3 2020, meaning that if EMA chose this location they would need to move into a transitional space following Brexit. However the alternative option would be able to be used by the EMA on 1 April 2019 and offers a functioning workplace for 1,300 people.
Accessibility of the location	Stockholm Arlanda Airport is the main international airport in the region, only 20 minutes from the proposed EMA office space, and offers direct flights to most EU capitals. There are also 3 other international airports offer more travel opportunities. There are 7,300 hotel rooms within a 10-minute walk of Stockholm Central Station.	Due to a more remote location there is more limited feasibility for day trips by experts visiting the agency relative to other cities and longer travel time from southern European countries.
Adequate education facilities	Sweden already has a wide and large range of international schools to offer, with teaching in a number of languages including English, German, French, Spanish and Dutch. There are also a number of pre-schools and nurseries near the building locations.	Limited information on availability of places in international schools to meet EMA's staff requirements.
Labour market, social security and medical care	Sweden offers safe and excellent working and living environments in a recognised open, tolerant, modern and multicultural society. The country ranks consistently high on the quality of life index, including having one of the highest overall life satisfactions (80%) and job satisfaction (77%) according to Eurostat. Healthcare access and quality is also rated very high at 90% (Lancet index). Sweden has one the strongest labour market in the whole of the EU and special matching activities will be arranged to facilitate entry to the labour market for accompanying family members of EMA employees.	None
Business continuity	The Swedish Medical Products Agency has 800 employees and intends to increase the number of employees in the coming years as a result of Brexit to support the EMA. Potential for resource synergies with the European Centre for Disease Prevention and Control (ECDC), located in Stockholm, to help further safeguard public health.	Compared to other bids the government has not provided a relocation timeline to illustrate specific milestones during the transition period.

VIENNA

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	Vienna has identified 8 existing potential properties that could be used for the base of the EMA and all properties can be modified to meet the requirements of the EMA.	Little information to suggest whether the existing office space could be modified to meet the conference demands of the agency.
Accessibility of the location	Vienna has excellent connectivity with direct flights to all EU capitals, with two thirds of cities reachable within 2 hours. It is feasible to do day trips to Vienna from 20 of Europe's capitals. Vienna has more limited connection to major US cities. Vienna is situated within driving distance from Bratislava, Budapest and Prague, and is also close to Bratislava airport, offering an alternative route for travel. Vienna offers plenty of capacity of EMA visitors across 439 hotels and 33,500 hotel rooms, with more hotels in development for 2019.	None
Adequate education facilities	Vienna has 9 International schools and 6 English language day centers across the city. Overall there is excess availability of spaces to cover the requirements for EMA staff. There are also a variety of pre-schools and nurseries across the city.	None
Labour market, social security and medical care	Vienna ranks highly on both safety, diversity and quality of life. The overall life satisfaction is 78% (Eurostat index) and healthcare access and quality id 88% (Lancet index). Vienna has many high-skilled employment opportunities in international companies.	Housing availability is more limited compared to other EU capitals and the government has made no specific provisions to assist staff in relocating.
Business continuity	The government has established a relocation timeline with interim milestones for testing office space and logistics prior to the move-in date.	Limited information on how the Austrian Medicines Agency could support EMA activities during the transition period. Today the NCA employs around 280 staff; a smaller number relative to other Member States, meaning it would have less capacity to backfill staff for EMA's activities.

WARSAW

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	The proposed office will be available from December 2018, in time for the Agency to take up its functions before the Brexit date. The space also provides considerable excess capacity for the EMA's activities.	No specifications of office space provided in the bid to understand if it will meet the EMA requirements (e.g. appropriately sized meetings rooms, archive space, security infrastructure etc.)
Accessibility of the location	Warsaw has very good connectivity with two international airports and day trip connectivity possible for many EU capitals. There are also direct flights to many international locations outside of Europe although more limited US or Japanese destinations.	Warsaw has fewer 4 and 5 star hotel options relative to other EU capitals.
Adequate education facilities	There are a number of American, European and International education facilities in Warsaw offering tuition in a foreign language. There are currently 2048 places in 44 public primary schools offering English, French, German or Spanish classes.	Limited information on availability of places in international schools to meet EMA's staff requirements.
Labour market, social security and medical care	Poland as a highly rated overall life satisfaction of 73% (Eurostat index) and a moderate-high rating of 80% for access and quality of healthcare (Lancet index). Over 2700 international companies operated from Warsaw in 2016 and there are a number of expat agencies and communities in Warsaw to provide assistance to staff family members.	Average median income in Poland is much lower compared to other EU economies, which may impact spouse finances.
Business continuity	Poland pledges to pay 50% of the rent and service charges for 10 years, in accordance with the given technical specifications.	The government has not provided a relocation timeline or detailed any specific assistance it will provide during relocation. There is also no information on whether the Polish national competent authority would be able to upscale its resources to support EMA's activities during the transition period.

ZAGREB

European Commission Criteria	How the criteria are met	Limitations in meeting the criteria
Adequate office logistics	The Croatian government has proposed the existing Sky Office building in Zagreb as the new location for the EMA that is only 20 minutes away from Zagreb international airport. The proposed space has an extra 5,000m^2 capacity over the existing office space in London, allowing for extra space should EMA need and expansion or additional resources.	Further adjustments are required to the existing infrastructure to meet EMA standards. The timeline for these refurbishments/when EMA staff can begin moving was not explicitly mentioned in the bid.
Accessibility of the location	Zagreb is centrally located in Europe and is driving distance from both Budapest and Ljubljana.	Zagreb international airport only offers direct flights to 50% of EU capitals, making accessibility fairly limited. Only 14 EU capitals fly directly to Zagreb, some of which only offer 1-2 flights per week. Day trip feasibility is only possible from two EU capitals: Vienna and Warsaw, and there are no international flights to cities such as Tokyo or Washington DC.
Adequate education facilities	Croatia offers a diverse range of public, private, and international schools that provide education in a foreign language. The ministry of science and education has proposed new educational institutions to accommodate the requirements for EMA staff.	Little information on current availability of places in International and European schools to support the needs of EMA staff.
Labour market, social security and medical care	Zagreb offers a low cost of living, high level of security, and a rich provision of cultural and social events. Croatia has a moderate overall life satisfaction of 63% (Eurostat index) a moderate-high rating of 80% for access and quality of healthcare (Lancet index).	Zagreb has a lower number of international companies present compared to other EU capitals, which may limit job opportunities for spouses.
Business continuity	Croatian government will set up an operational office that will be available for non-stop communication with the EMA to ensure business continuity and successful implementation. This also includes family support such as assistance in finding employment for partners/family members.	The Agency for Medicinal Products and Medical Devices of Croatia (Halmed) has a development strategy to increase its scope of activities and international collaboration by 2018. However to date, the more limited experience of the agency in these activities may impede its ability to support EMA during the transition period. Croatia has a small biopharmaceutical presence relative to other EU Member States.