

Ministry of Health, Welfare and Sport

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Secretary-General of the Council of the European Union
Mr Jeppe Tranholm-Mikkelsen

Secretary-General of the European Commission
Mr Alexander Italianer

**Directorate-General
Curative Care**
Department of
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Our reference
1184151-166458-GMT

Your reference
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Enclosure(s)
2

Date July 28, 2017
Subject Dutch bid to host the European Medicines Agency (EMA)

*All correspondence addressed
to the postal address quoting
date and reference of this
letter.*

Dear Mr Tranholm-Mikkelsen, dear Mr Italianer,

On behalf of the Dutch government we have the pleasure of submitting to you the Dutch bid to host the European Medicines Agency (EMA), which will move from London as a consequence of the UK's decision to leave the European Union. The Dutch Government offers the Amsterdam Metropolitan Area as the new location for the headquarters of the Agency. Our bid is based on four key aspects: Continuity, Connectivity, Commitment and Community, as worked out in the bid book annexed to this letter.

We have carefully examined the criteria as endorsed by the European Council (art. 5) on 22 June 2017¹. In this letter you can find a summary of how the Netherlands has addressed these criteria as well as the additional requirements that need to be taken on board in the official bid.

Attached to this letter you can find a separate confidential annex, holding certain business sensitive aspects of the bid. Finally, this letter, the confidential annex and the enclosed bid book together form the Dutch bid to host the European Medicines Agency. Further details and a short video can also be found on the website of the Dutch EMA candidacy.²

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

With this bid, the Netherlands ensures EMA that it can take up its functions at the date of withdrawal of the United Kingdom from the European Union by offering the Vivaldi Building at Amsterdam Zuidas as its new headquarters. The Vivaldi Building is a brand new office building that is custom designed to meet all EMA's needs and that matches all specifications as laid down in the factsheet of the above mentioned Council document. As the conference facilities in the new building are

¹ Council of the European Union, 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; doc. XT 21046/17, 22 June 2017.

² Website for the Dutch EMA candidacy: www.netherlandsforema.eu.

of key importance to ensure continuation of EMA's scientific work, these will be available to the Agency and operational at the removal date, currently foreseen at 1 April 2019. The remaining office floors holding workstations will become available at a regular pace in the six months following the removal date. To ensure that EMA can function without disruption, during this transition period the Agency will be able to work from a fully-fledged temporary office location in the nearby vicinity of the new headquarters.

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The temporary office location will be available as of 1 January 2019 or earlier if required by EMA. The temporary office location offers workstations for all EMA staff with a total floor size of 10,000 to 16,000 m². The exact floor size and required number of workstations will match EMA's needs and include flexible working spaces (e.g. hotdesking) and/or fixed office spaces for the Agency's staff. The temporary office location will be fully furnished and have adequate facilities in place such IT and AV infrastructure, restaurant and car parking. The temporary location will provide a range of meeting rooms for 8-20 participants for smaller expert and/or staff meetings, while the conference centre in the Vivaldi building will be available for the larger scientific meetings. Further details on the temporary office location can be found in the confidential annex to this letter. The details on the new headquarters itself can be found in the "Continuity" section and in the building annex of our bid.

With this approach, the Netherlands offers EMA a transition proposal that allows for full business continuity with minimal disruption during a fixed period of time, while no refurbishment or adjustment of the building will be required once the Agency has moved in.

Criterion 2 - The accessibility of the location

The accessibility of Amsterdam, and with it both the Vivaldi Building and the temporary office location, is unparalleled. As indicated in our bid, Amsterdam Airport Schiphol has a large number of direct flight connections to and from all EU Member States. Both office locations are located at only 10 minutes travelling distance from the airport. Local ground transportation to the locations but also to the surrounding regions and to international school facilities is excellent. For EMA visitors and experts over 5,000 hotel rooms will be available by 2019 in the immediate vicinity of the Agency's new headquarters at Amsterdam Zuidas. In total, 41,000 hotel rooms are currently available in the broader Amsterdam Metropolitan Area and another 11,000 rooms will be added by 2020. For further details, please refer to the "Connectivity" section in our bid.

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

The Netherlands is one of the few EU Member States with a rapidly expanding capacity at international schools. As part of a master plan for international education (the 'Delta Plan') new British and international schools are opening in the Amsterdam Metropolitan Area in the next two years, adding thousands of places to the existing capacity. At commuting distance from the new headquarters, over 22 international schools can be found, offering high quality primary and secondary education at relatively low costs. Apart from private international schools, the Netherlands also offers a unique system of publicly funded international schools with high quality education. The two European schools in the

Netherlands (The Hague and Bergen) have indicated they can expand their capacity with hundreds of places in case EMA relocates to the Netherlands. In short, although capacity at international schools in most EU countries is usually scarce, capacity in the Netherlands is growing rapidly. We feel confident that EMA staff will find the education of choice for their children in our country. Further details on education facilities can be found in the "Community" section of our bid.

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Criterion 4 - Ensuring appropriate access to the labour market, social security and medical care for both children and spouses of EMA staff

The Netherlands is a highly attractive country for international companies. The city of Amsterdam and the greater Amsterdam Metropolitan Area, but also the cities of Leiden and The Hague see a steady increase of international companies and international organisations.

The relocation programme offered by the Netherlands to EMA staff and their families will provide full service on an individual family basis on all relevant aspects providing for a seamless transition and settling in. This will be realised by building on the already successfully operating expat service centres in Amsterdam, Leiden and The Hague. All services will be provided by a single point of contact for each family and will commence from the first day after the relocation decision has been taken by the Council. It entails that support and advice will be given to families on how to gain access to the local labour market, what formalities need to be addressed to ensure access to social security and how to gain access to high quality medical care in the Netherlands. The Joint Sickness and Insurance System (JSIS) of the European Commission offers EMA staff access to social security and healthcare in the Netherlands. Further details on the labour market, social security and medical care for children and spouses of EMA staff can be found in the "Community" section of our bid.

Criterion 5 - Business continuity and the transition plan

In the running up to this bid and the decision-making procedure for the relocation of EMA, the Netherlands have emphasised that business continuity is of key importance to ensure that the Agency's operations can continue with minimal disruption, to avoid any negative consequences for patients in Europe.

In this bid, the Netherlands expresses its commitment to ensure such business continuity in case the Netherlands is chosen as EMA's new host country. Our approach is that of unburdening and fully supporting the move of the EMA headquarters from London to Amsterdam as well as the relocation of EMA staff and their families to our country.

The Central Government Real Estate Agency (CGREA) and the city of Amsterdam are already undertaking all actions to fulfil the necessary procedures and building requirements. This includes legal aspects, spatial planning, site preparation and preparation of the EU tendering procedures up to the technical design of the Vivaldi Building. CGREA has ample experience with fast-track building processes for international organisations. This approach enables us to offer EMA all necessary support from the first day after the relocation decision by the Council so that the Agency can prepare its move to the Netherlands effectively and timely. This may include staff from both Agencies working together on both sides of the Channel, but also support in all legal and building related matters and questions

regarding the resettlement of the Agency in the Netherlands. This support is critical as EMA will have very little time to find its way in its new home country, including regarding the real estate market and legal situation. The services of CGREA will save months of preparation, staff time and consultancy costs in comparison to a situation in which the Agency has to get acquainted with the legal and commercial real estate environment on its own in the new host country. The Dutch government has already allocated € 1.4 million to offer the services of CGREA to support the relocation of the Agency to the Netherlands from the day after the Council has decided on relocation and throughout 2018 and 2019.

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The Dutch government and the city of Amsterdam in particular, will offer individual assistance to the Agency's staff in relocating to the Netherlands. This assistance involves a relocation programme that includes regular information sessions for EMA staff in London, the opening of a help-desk for EMA staff in London, individual support to EMA staff and families as well as support after settlement. This relocation programme will also begin immediately after the decision of the Council to move the Agency to the Netherlands. The estimated costs of € 4.25 million for this programme will be covered by the city of Amsterdam and the Dutch government.

In addition to the support to the relocation of the EMA headquarters and its staff, the Netherlands are also committed to ensure business continuity for the scientific work of the Agency and the EU network of national medicines regulatory agencies. Therefore the Dutch Medicines Evaluation Board, one of the top contributors to the network and already accounting for almost one-fifth of the scientific expert work of EMA, has received additional funding of € 2 million to expand its scientific capacity so that it can take up more procedures at EU level. Furthermore, the Dutch MEB is ready to support EMA in its daily business, in a similar way as currently offered by the British authorities. In order to strengthen the EU network, cooperation strengthening both existing training capacity facilities but also bilateral cooperation will be set up, supporting EU countries with limited scientific capacity to expand. For this cooperation programme, the Dutch government has allocated € 8.1 million over the next three years.

Please refer to the "Commitment" section in our bid for further details, including a detailed planning for the transition phase beginning directly after the Council decision on relocation of the Agency until the moment at which the EMA new headquarters is fully operational.

Criterion 6 - Geographical spread

The Netherlands is fully aware of the earlier commitment expressed at EU Council level in 2003 and 2008 to ensure that new EU agencies should in principle be geographically spread across the European Union, in particular to EU countries without any agencies. At the same time, the Netherlands argues that the movement of EMA, a large and fully operational agency and scientific 'hub', is unique, in particular also given the uncertainties and circumstances related to the Brexit. In 2012 the European Parliament, Council and Commission reached an agreement to make relocation decisions on EU agencies more objective. The Netherlands respectfully believes that the business continuity and retention of expert staff is in this case more essential for the functioning of EMA. We are convinced that this is in the favour of all European citizens and patients. In addition, we think it is important to strengthen the capacity within the network of

national agencies in order to reach a better balance in the workload and expertise among the different EU member states. We believe the EU27 has the responsibility to ensure EMA's functioning in the long run.

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General issues related to the bid

Seat agreement

As indicated in the attached bid, the Netherlands is ready to include the key aspects from its bid into a seat agreement between the Netherlands and EMA. The negotiations on this agreement can begin immediately after the decision of the Council on relocation of the Agency. The seat agreement could be signed by EMA and the Dutch government as early as May 2018.

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Any benefits granted to the Agency and its staff

The privileges and immunities that will be part of the seat agreement will include the conditions as adopted in Protocol no. 7 TFEU. In addition, they will be adapted to the specific needs of EMA, equivalent to those agreed with the existing EU institutions in the Netherlands.

For further details on the seat agreement and privileges and immunities, please refer to the "Commitment" section in our bid.

Financial terms for EMA's use of the Vivaldi building and the temporary office location

The Vivaldi Building at Amsterdam Zuidas will be developed by the Central Government Real Estate Agency specifically for EMA. The Agency will subsequently lease the building from the CGREA. The duration of the lease, costs, maintenance and any other specific terms related to the lease are negotiable and will be laid down in a headquarters agreement between EMA, the Ministry of Health, Welfare and Sport and the CGREA.

EMA is an independent and professional EU agency that is well funded through fees from operators in the pharmaceutical market and to a smaller extent through the EU budget. As a consequence, the Dutch government considers it unnecessary to offer the Agency structural financial support. However, in order to ensure a seamless relocation of EMA to the Netherlands and to compensate for double costs during the transition period (such as the temporary office location), the Netherlands is willing to offer the Agency a one-off financial incentive of € 18 million for its new headquarters.

This sum will be made available to the Agency and can be used by EMA:

- To cover the lease costs of the temporary office location in 2018/2019, and;
- For a rent-free period, as a contribution to cover a part of the fitting costs of the new building or for an overall reduction of the annual lease for the duration of the lease agreement.

Terms for maintenance including upgrading & future extensions

As EMA will lease its new headquarters from the CGREA, as owner of the building the CGREA will maintain the building in accordance with the high standards it also applies to Dutch government buildings. As the building is custom developed for EMA and has a spacious design, upgrading or extensions will probably not be necessary for a considerable number of years. Should EMA have a need for such changes in the future, these can be realised in cooperation between the Agency

and CGREA. Recent experiences with existing EU agencies in the Netherlands have shown very satisfactory outcomes.

Any special conditions offered with regard to all costs and dedicated infrastructure

As indicated in our bid the Vivaldi Building will be custom designed to EMA's needs. EMA can close a services agreement with the CGREA according to its needs. All necessary infrastructures will be available at the new premises. As the Vivaldi building will be developed as a near energy neutral building, energy costs will be very low.

For further details on the new EMA headquarters and the financial conditions for the new premises, please refer to the "Continuity" section in our bid.

Final remarks

We are convinced that with this bid the Netherlands offers a complete package for the relocation of EMA to our country. We therefore look forward to the outcome of the assessment of the European Commission of the bids offered by all Member States that propose to host EMA.

Yours sincerely,

mw. drs. E.I. Schippers
Minister of Health, Welfare and Sport

dhr. B. Koenders
Minister of Foreign Affairs

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Annex 1: Offer for EMA – CONFIDENTIAL ANNEX - NOT FOR PUBLICATION

Annex 2: Dutch bid to host the European Medicines Agency