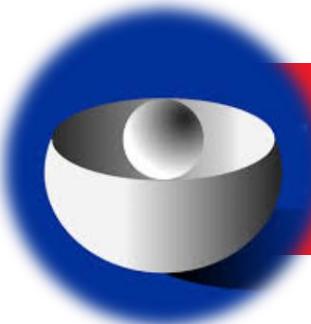




Gevolgen voor (klinisch) onderzoek naar genees- en hulpmiddelen





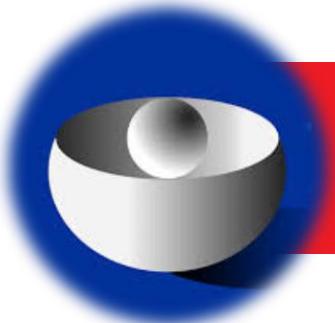


amsterdam®





EMA naar Amsterdam





2989



891



Gross Value Added

€ 193m

EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH



an 'ecosystem' of about 2,500 companies in the 'life sciences and health' sector has grown up around the EMA in London



EMA ‘location bias’ (?): delivered benefits for the wider LSH sector in the UK

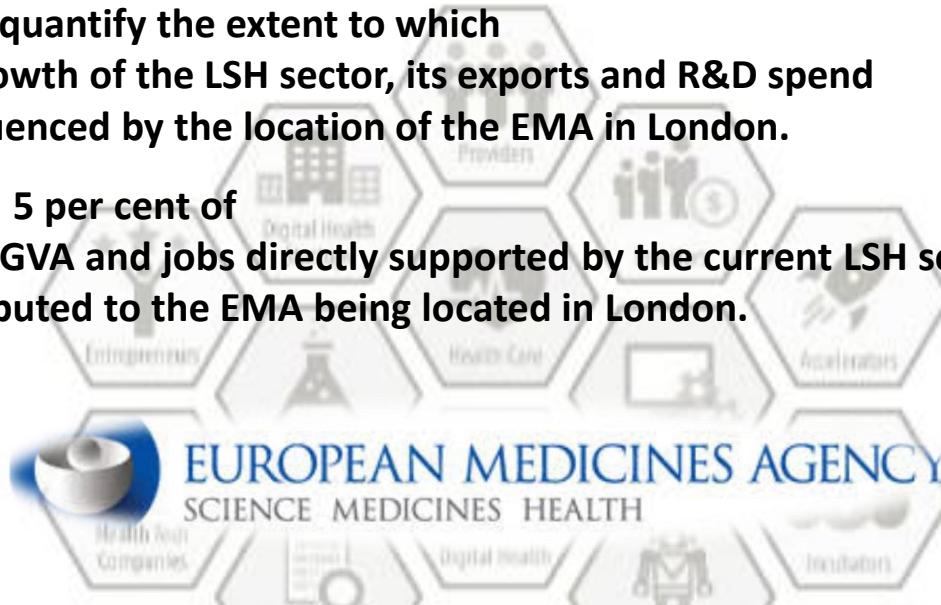
- The EMA is believed to have **contributed to the development of the LSH sector’s industrial base in the UK**
- UK regulators, and **the regulatory supply chain, have benefited from the close proximity of the EMA**
- The EMA has also **contributed to the ‘pull-factor’ of the UK in attracting LSH companies**
- The EMA has improved knowledge sharing in the UK through formal and informal channels
- There are **some strategic advantages to the UK in relation to the regulatory approval process and collaborative working with US and Japanese regulators**
- The location of the EMA has **little impact on the clustering of universities, and the extent to which clinical trials and R&D activities are undertaken in the UK**
- The UK’s influence on regulatory/legislative issues is not significantly enhanced by the presence of the EMA
- The views on the **influence of the EMA on the UK’s international position in research, technology and development (RTD)** are not conclusive



Analysis of effects in case of
relocation of
the European Medicines Agency (EMA)
to the Netherlands

 it is difficult to quantify the extent to which
the size and growth of the LSH sector, its exports and R&D spend
have been influenced by the location of the EMA in London.

 1 per cent and 5 per cent of
the revenues, GVA and jobs directly supported by the current LSH sector
might be attributed to the EMA being located in London.



Indicator	Current size of the LSH sector	Indicative attribution to EMA location in London	
		%	Direct impact of EMA on LSH sector
Employment	180,000 FTE jobs	1%-5%	1,800 – 9,000 FTE jobs
GVA	€10bn per annum	1%-5%	€100m – €500m per annum
R&D spend	€16bn per annum	1%-2.5%	€160m – €400m per annum





EMA ‘location bias’: delivered benefits for the wider LSH sector

If the EMA were to transfer to other EU Member States,
the appeal of London as an environment for the development of pharmaceuticals would be lost,
which could possibly lead to a shift in the flow of R&D funds and personnel to Continental Europe.

This could force Japanese companies to reconsider their business activities.

[Ministry of Foreign Affairs of Japan](#)



2989



891



2538



891

Gross Value Added
€ 193m

Many companies like to have offices close to us. We have seen this happen in London, and it will happen again in Amsterdam too. An organisation such as ours is a nucleus for new activities in related health areas, and our presence is an extra reason for companies and institutions to stay and invest more.'



amsterdam®

Gross Value Added
€ 135m



EMA LONG TERM IMPACTS

The relocation of the EMA could also provide long-term impacts for the LSH sector in the Netherlands including:

- an increased pool of regulatory talent and skills;
- a closer relationship between the EMA and the Medicines Evaluation Board (MEB);
- the relocation of some private sector operations and service providers from the UK;
- reduced travel costs for Dutch SMEs and regulators;
- increased informal contacts with the EMA;
- and reputational benefits from hosting the EMA.

There is considerable uncertainty associated with the potential scale of these impacts, although they could support additional growth of GVA and employment in the LSH sector of between 1 per cent and 5 per cent per annum.



Analysis of effects in case of
relocation of
the European Medicines Agency (EMA)
to the Netherlands



Indicator	Current size of the LSH sector in NL	%	Indicative growth due to EMA relocation Direct Impact of EMA on LSH sector in NL
Employment	34,000 FTE jobs	1%-5%	340 – 1,700 FTE jobs
GVA	€3.3bn per annum	1%-5%	€33m – €165m per annum
R&D spend	€5.0bn per annum	1%-2.5%	€50m – €125m per annum



[...]: 'Ik ben betrokken bij de oprichting van drie bv's voor een biotechbedrijf dat anders vanwege de *Brexit* naar Ierland was gegaan, maar dankzij de verhuizing van het EMA heeft gekozen voor Amsterdam.'

Advocatenblad 2018-04.





TOPICS NIEUWSBRIEF DIGITAL

Vrij, Onverveerd
Het Parool

HOME AMSTERDAM OPINIE STADSGIDS

EMA blijkt nu al banentrekker te zijn



PLUS

De betonnen kern van de EMA-toren aan de Zuidas bereikte deze week het hoogste punt: 80 meter © Tammy van Nerum



Europees medicijnbureau EMA is nog niet eens in Amsterdam geland of farmabedrijven staan al in de rij om naar de hoofdstad te komen. De tussenstand: ruim 1200 banen erbij.

DOOR: HERMAN STIL 22 SEPTEMBER 2018, 12:00



gevolgen verhuizing EMA / actuele verwachtingen

- Niet-kernactiviteiten EMA worden tijdelijk teruggeschroefd
- Deel personeel komt niet mee → verlies expertise
- Er komen vacatures, maar voor experts uit heel Europa
(3.500 open sollicitaties)

- “Doe mij graag wat Hollandse nuchterheid”
- Nederland krijgt niet meer invloed op de EMA
 - Nederland krijgt wel meer aanzien en gewicht in LS&H veld
 - Impact op LS&H hangt mede af van andere factoren, zoals:
onderzoekscapaciteit, procedures, vermarkten onderzoek



The word "BREXIT" is written in large, bold, capital letters. The letters are filled with the colors of the Union Jack flag (Red, White, and Blue) and the European Union flag (Blue with yellow stars). The letters are slightly jagged, suggesting a sense of fragmentation or breaking apart.





BREXIT

medische producten



Gevolgen BREXIT

Afhankelijk van scenario:

BREXIT Deal

- ❖ overgangsperiode tot 1 januari 2021
- ❖ inhoud bepaalt gevolgen

BREXIT NO Deal

- ❖ “cliff edge”





CLIFF EDGE

Verenigd Koninkrijk:

- Brexit 'derde' land → geen onderdeel Interne Markt of douane unie;
- Brexit EU regelgeving i.e. medische producten, klinische proeven, data, privacy niet langer van toepassing / bindend→
 - Brexit Britse toezichthouder niet langer EU competent authority genees- en hulpmiddelen;
 - Brexit VK doet niet meer mee met (lopend) EU gefinancierd wetenschappelijk onderzoek;
 - Brexit VK valt buiten het netwerk onder de Clinical Trial Regulation;
 - Brexit VK heeft geen toegang meer tot en zal niet meer bijdragen aan EU databases v.v.
 - Brexit Patiënt- en onderzoeksdata mogen niet meer worden overgedragen of gedeeld met Britse onderzoeksinstellingen
(Algemene verordening gegevensbescherming (AVG))



CLIFF EDGE



https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#grow



Department
of Health &
Social Care

<https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal>



Gevolgen BREXIT

Wegvallen van VK capaciteit

BREXIT beoordeling en autorisatie

BREXIT richtlijnontwikkeling

BREXIT rapporteurschap CTR

BREXIT wetenschappelijke 'excellence'

KANSEN ZIEN, KANSEN PAKKEN

Holland vestigingsklimaat,
Holland onderzoekscapaciteit,
Holland doelmatige procedures,

Holland samenwerken





**KANSEN ZIEN,
KANSEN PAKKEN**

 **samenwerken**



Health~Holland 



Bedankt voor jullie aandacht!



Maurice Galla ms.galla@minvws.nl

Ed Jansen ej.jansen@minvws.nl