



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2018 EMA-Industry Stakeholder interactions on Brexit related topics

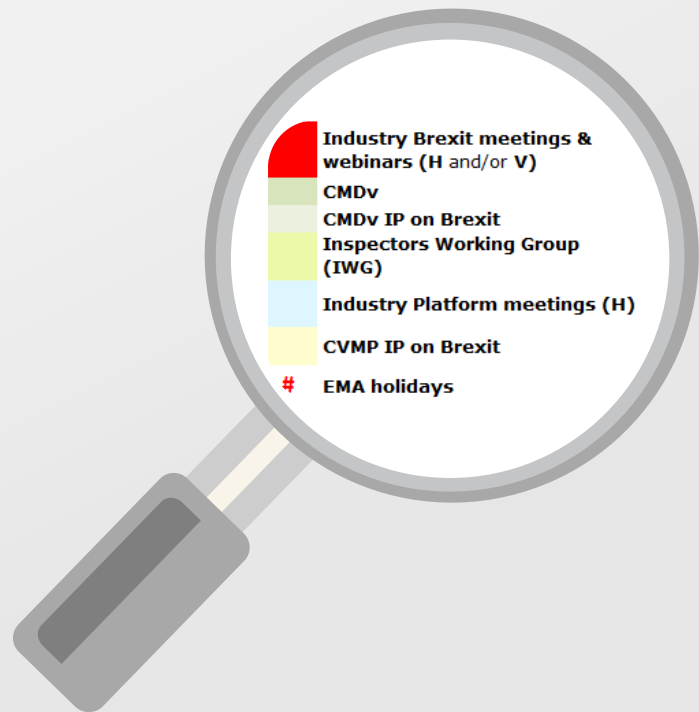
Brexit regulatory preparedness for veterinary medicinal products
in the centralised procedure

Presented by Dr. Marie-Helene Pinheiro on 20 April 2018
Industry Stakeholder Liaison

An agency of the European Union



2017 calendar



September						
S	M	T	W	T	F	S
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	3	4	5	6	7	8 9
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Veterinary

October						
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Veterinary

November						
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Veterinary

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31						

Veterinary



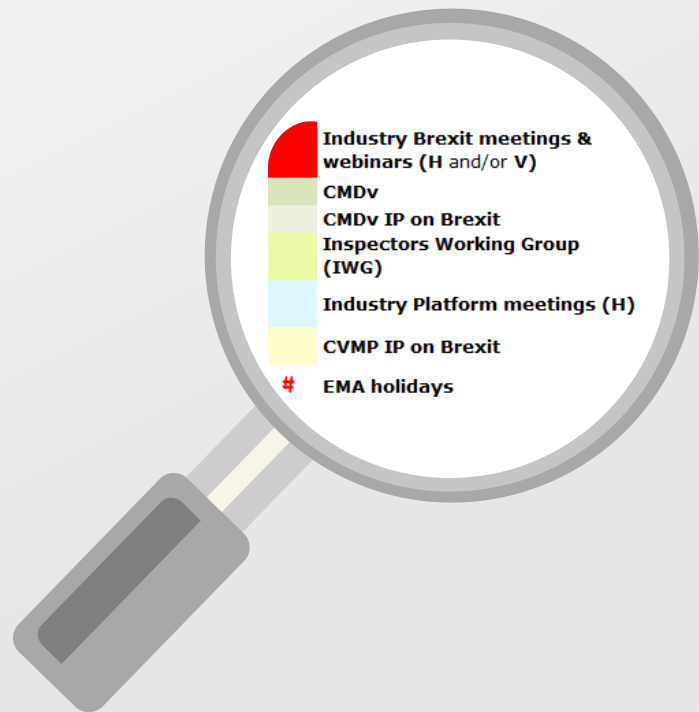
*Publication of 20 April meeting **high level summary report** by end of May 2018 (tbc)*

*Expected publication of **EC/EMA Q&A** and **EMA procedural guidance***

2017-2018	Publication of EC Q&A update - EMA procedural guidance - EMA Survey
02.05.17	Publication of EC/EMA Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use
31.05.17	Publication of EC/EMA Q&A related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure
27.11.17	EMA Practical guidance for procedures related to Brexit for medicinal products for human and veterinary use within the framework of the centralised procedure
01.12.17	Publication of EC/EMA Q&A related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure 1st update
23.01.18	Launch of EMA Brexit Industry Survey to Centralised MAHs (<i>UK affected</i>)
Q2 2018	<i>Publication of EC/EMA Q&A related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure, 2nd update</i>
Q2 2018	<i>EMA Practical guidance for procedures related to Brexit for medicinal products for human and veterinary use within the framework of the centralised procedure, 1st update</i>
By end May 2018	EMA Brexit Industry survey analysis and high level summary publication



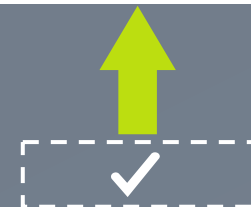
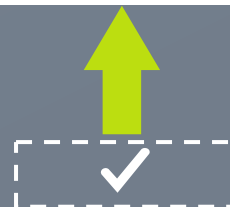
2018 calendar



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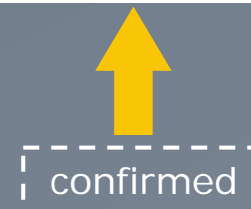
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September						
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November						
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Request interaction via e-mail to:

[vet.applications@ema.europa.eu](mailto:veterinary.applications@ema.europa.eu) having previously consulted the published

- ▶ [European Commission/EMA questions and answers](#) and
- ▶ [EMA procedural guidance](#)

- a. With “Brexit company’s” preparedness plan description
- b. Specific “Brexit” Questions and Company’s position
- c. Proposed meeting dates

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For more general questions not related to any particular centralised application/product, use **AskEMA** (using the [web-form](#))

Veterinary Medicines





Any questions?

Further information

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