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

2017 EMA-Industry Stakeholder interactions on Brexit related topics

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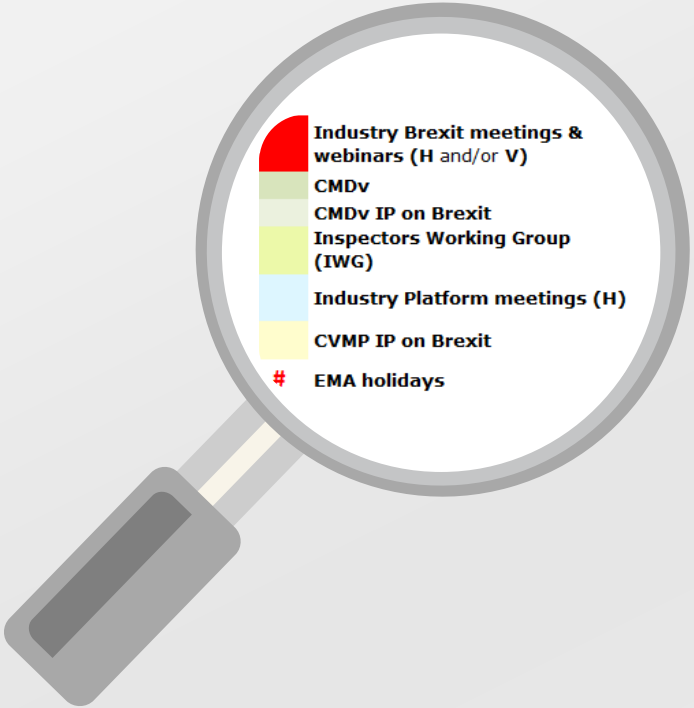
2017 calendar



September

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Veterinary

October

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Veterinary

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Veterinary

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Veterinary

Brexit regulatory preparedness for veterinary medicinal products in the centralised procedure

2017-2018 EMA-Industry Stakeholder interactions on Brexit related topics

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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 *(UK affected)*
Q2 2018	*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***
Q2 2018	***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***
By end May 2018	EMA Brexit Industry survey analysis and **high level summary publication**

2018 EMA-Industry Stakeholder interactions on Brexit related topics

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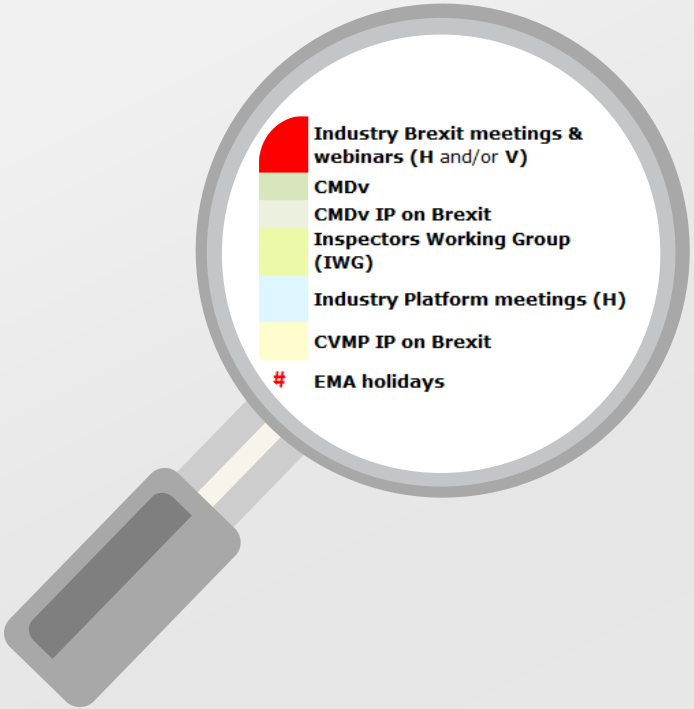
2018 calendar



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tentative

September

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tentative

October

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confirmed

November

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tentative

EMA–Company specific interactions on Brexit

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Veterinary Medicines

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Request interaction via e-mail to: **vet.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)

Any questions?

Further information

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