



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2018 EMA-Industry Stakeholder interactions on Brexit related topics

Industry Stakeholder meeting on Brexit and operation of the centralised procedure for human medicinal products

Presented by Marie-Helene Pinheiro on 23 March 2018
Industry Stakeholder Liaison, Corporate Stakeholders
Stakeholders and Communication





*Publication of 23 March meeting
high level summary report
by end of April 2018*



*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



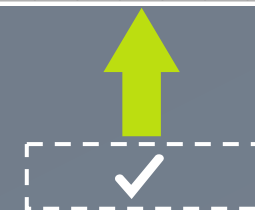
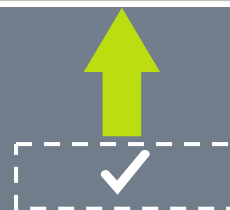
2018 calendar



March						
S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

April						
S	M	T	W	T	F	S
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8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

July						
S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				



September						
S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

October						
S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

November						
S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	





Any questions?

Further information

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