



# **Technical seminar on BREXIT Pharmaceuticals related issues**

**Brussels, 8 March 2018**

# Intervention HMA BREXIT Task Force

# Brexit

## *Preparedness Measures HMA*

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# Outline



- 1. Brexit basic assumptions*
- 2. HMA Brexit Task Force composition*
- 3. HMA Brexit Task Force mandate*
- 4. HMA/EMA Joint Brexit message*
- 5. MRP/DCP capacity survey*
- 6. Overview Brexit preparations HMA Working Groups*
- 7. Collecting Q and A's on Brexit*
- 8. Meeting schedule 2018*

# 1. Brexit – basic assumptions

- *Starting point for all preparations: United Kingdom will leave European Union on 29 March 2019, thereby becoming a 'third country'.*
- *Transition phase underway: only 13 months left to get prepared.*
- *Any extension of transition phase is speculative: preparing for 'hard' Brexit scenario is only option to guarantee regulatory continuity.*



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## 2. HMA Brexit Task Force

- *Composition BTF: 18 heads of agencies, chairs CMDh and CMDv*
- *Chair: Hugo Hurts (MEB) – Co-chair: Thomas Heberer (BVL)*
- *Meeting frequency BTF: every two months (6 times per year)*
- *BTF operational as of HMA II in Tallinn (November 2017)*



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## 3. Mandate

### *The HMA Brexit Task Force:*

- *Prepares the network for the worst case Brexit-scenario with a focus on decentralized activities and practical issues.*
- *Builds up oversight in order to ensure regulatory continuity of the network, including reference to available Q&A's (EMA, CMDh, CMDv, European Commission).*
- *Avoids any duplication of work and lines up with EMA/HMA/CMD actions as much as possible.*
- *Identifies outstanding issues in Brexit preparations and involve relevant groups and bodies.*
- *Considers industry preparedness in its recommendations and proposed actions.*



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## 4. Joint Brexit message

### *HMA/EMA Joint Brexit message to third parties*

- *BTF mandate: to ensure a coordinated approach within the network to safeguard regulatory continuity.*
- *Joint HMA/EMA Brexit message to third parties developed.*
- *Input requested from: HMA BTF members, EMA, CMDs, TF on Availability.*
- *Focus: call for action to Marketing Authorization Holders.*
- *Next step: process input and finalize message for publication.*





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## 5. MRP/DCP capacity survey

### ***HMA/EMA survey into MRP/DCP capacity and training needs***

- *BTF mandate: prepare the network for Brexit with a focus on decentralized activities.*
- *Survey-focus: DCP/MRP capacity and training needs of the network.*
- *Follow-up to survey on central capacity of June 2017.*
- *NCA's have delivered input on set-up and formulation through BTF.*
- *Timeline: survey to be conducted in March.*



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## 6. HMA Working Groups

### ***Overview Brexit preparations HMA Working Groups***

- *BTF mandate: to build up oversight in order to ensure regulatory continuity of the network.*
- *Query on Brexit-preparations sent to Working Group chairs.*
- *Responses collected in comprehensive overview.*
- *Next step: analyse Brexit-preparations and identify possible missing elements.*

## 7. Collecting Brexit Q and A's

### *Collecting Q and A's on Brexit*

- *BTF mandate: coordinate Brexit queries and the coordination groups' responses to them.*
- *Existing Q and A's collected and presented in overview.*
- *Next step: scan for possible inconsistencies, enhance visualization, update when appropriate.*



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# 8. Meeting schedule 2018



Date	Time	What
Thursday 25 January	11:00-12:30 CET	Teleconference
Wednesday 28 February	14:00-15:00 CET	HMA Face-to-face meeting (HMA I Lisbon)
Thursday 3 May	13:00-14:30 CET	Teleconference
Wednesday-Thursday 20-21 June	TBD	HMA Face-to-face meeting (HMA II Sofia)
Wednesday 19 September	14:00-15:30 CET	Teleconference
Thursday 20-21 Friday 23 November	TBD	HMA Face-to-face meeting (HMA II Vienna)