Lyfjastofnun
Icelandic Medicines Agency

Brexit

Fundir með hagsmunaaðilum

Janúar 2019

Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, as endorsed by leaders at a special meeting of the European Council on 25 November 2018

1

Council of the
European Union

Brussels, 22 November 2018
(OR. en)

XT 21095/18

BXT 111
CO EUR-PREP 54

NOTE

om:	General Secretariat of the Council
:	Delegations
bject:	Political declaration setting out the framework for the future relationship between the European Union and the United Kingdom

legations[1] will find in the Annex the Political declaration setting out the framework for the future
ationship between the European Union and the United Kingdom. This declaration has been
eed at negotiators' level and agreed in principle at political level, subject to the endorsement of
Leaders.

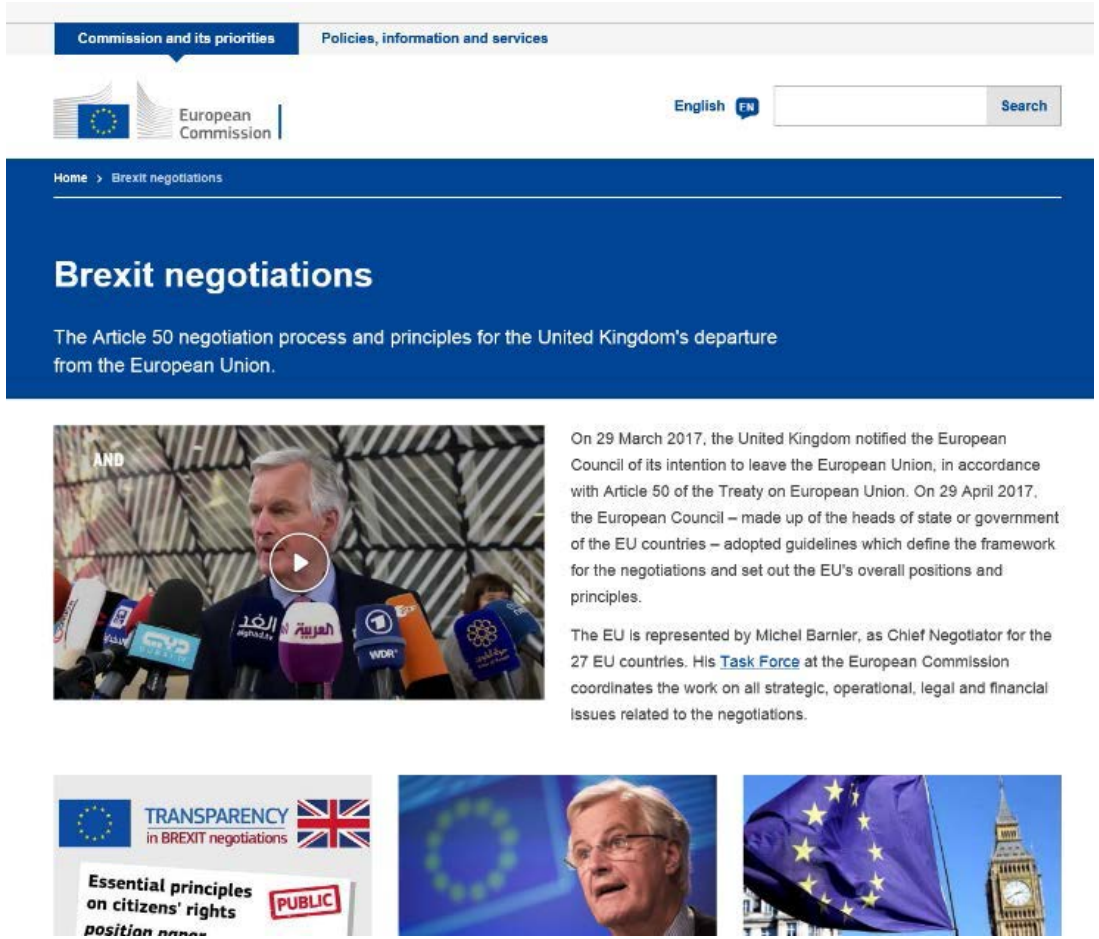
[1] Following a notification under Article 50 TEU, the member of the European Council or of the Council representing the withdrawing Member State shall not participate in the discussions of the European Council or Council or in decisions concerning it.

Hvar eru upplýsingar um áhrif Brexit?

Framkvæmdastjórnin

https://ec.europa.eu/commission/brexit-negotiations_en

- Upplýsingar um samningaviðræður
- Samningsdrög 14.11.2018
- Aðlögunartími til 31.12.2020 - eða lengur?
- Spurningar og svör
- Fréttatilkynningar



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EMA

https://www.ema.europa.eu/en/about-us/uks-withdrawal-eu/brexit-related-guidance-companies

- Spurningar og svör frá EMA
- EMA leiðbeiningar um Brexit
- Fundagerðir
- Fréttatilkynningar
- Niðurstöður úr könnunum um Brexit
- Endurúthlutun á matsaðilum ((co) Rapporteur)

Guidance for companies

Relocation to Amsterdam

Brexit-related guidance for companies

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- Guidance on centrally authorised products
- Industry survey (for centrally authorised products)
- Guidance on nationally authorised products
- Stakeholder meetings

The European Medicines Agency (EMA) and the European Commission are providing guidance to help pharmaceutical companies responsible for both human and veterinary medicines prepare for the United Kingdom's (UK) withdrawal from the European Union (EU), a process known as 'Brexit'.

This aims to ensure that companies are ready to take the necessary steps to enable **undisrupted supply** of their medicines in the EU for the **benefit of patients**, based on the assumption that the UK will become a third country as of 30 March 2019.

Guidance on centrally authorised products

Companies should **check this page regularly** for guidance on the consequences of Brexit, as EMA and the European Commission are preparing a series of guidance documents.

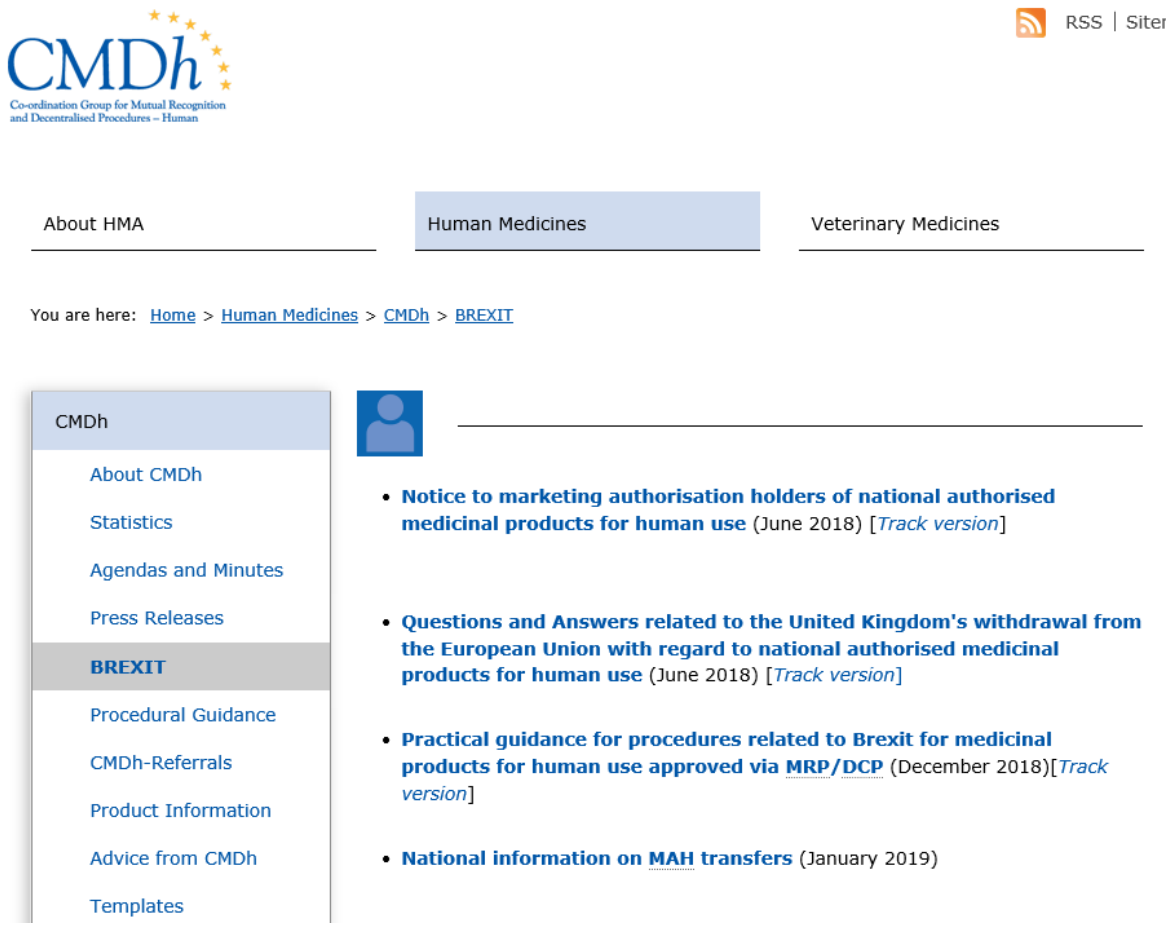
Document	Contains information on	Last updated
	• location of entities, including: ◦ marketing authorisation holders and applicants; ◦ orphan designation holders;	

CMDh/CMDv

CMDh http://www.hma.eu/535.html

CMDv http://www.hma.eu/542.html

- Spurningar og svör
- Brexit leiðbeiningar og ferlar
- Sniðmát (template) fyrir RMS-færslu



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Bretland

Brexit síða:
https://www.gov.uk/government/brexit

Upplýsingar ef enginn samningur verður gerður:

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

Upplýsingar ef samningur verður gerður /aðlögunartími:

https://www.gov.uk/government/publications/implementation-period-what-it-means-for-the-life-sciences-sector


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Department of Health & Social Care

Guidance

How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal

Updated 14 September 2018

Contents

Purpose

Before 29 March 2019

After 29 March 2019 if there's no deal

Implications

More information

A scenario in which the UK leaves the EU without agreement (a 'no deal' scenario) remains unlikely given the mutual interests of the UK and the EU in securing a negotiated outcome.

Negotiations are progressing well and both we and the EU continue to work hard to seek a positive deal. However, it's our duty as a responsible government to prepare for all eventualities, including 'no deal', until we can be certain of the outcome of those negotiations.

For two years, the government has been implementing a significant programme of work to ensure the UK will be ready from day 1 in all scenarios, including a potential 'no deal' outcome in March 2019.

It has always been the case that as we get nearer to March 2019, preparations for a 'no deal' scenario would have to be accelerated. Such an acceleration does not reflect an increased likelihood of a 'no deal' outcome. Rather it is about ensuring our plans are in

Hvað þarf að vera innan EES?

Innan EES

- Markaðsleyfishafi
- Umsækjandi um markaðsleyfi
- RMS
- Sponsor fyrir „orphan lyf“
- QPPV og PSMF (Pharmacovigilance System Master File)
- SME (verkefni um lítil og meðalstór fyrirtæki)
- Prófun og losun (Batch testing and release)
- „Supervisory authority“ GMP
- Bretland verður „þriðja land“ m.t.t. framleiðslu á hráefnum og innflutnings á tilbúnum lyfjum.

Hvað þurfa markaðsleyfishafar að gera? 1/2

- Halda áfram að búa sig undir „hart Brexit“ þ.e. ekki gera ráð fyrir aðlögunartíma
- Skoða hvort Brexit geti haft einhver áhrif á markaðsleyfið
  - T.d. staðsetningu á MLH, losunarstað, prófunarstað o.s.frv.
- Upplýsa yfirvöld um hugsanlega hættu á skorti vegna Brexit
- Ef Bretland (UK) er viðmiðunarland (RMS) þá þarf að flytja RMS
  - Hafa samband við CMDh/v ef það eru vandræði við að finna nýtt RMS

Hvað þurfa markaðsleyfishafar að gera? 2/2

- Aðlaga ferla og gera nauðsynlegar breytingar svo markaðsleyfi verða gild og engin vandkvæði við innflutning eftir Brexit
- Senda nauðsynlegar breytingaumsóknir vegna Brexit
  - E.t.v. ræða við lyfjastofnanir um tímasetningar á innsendingum
- Ljúka umsóknarferlum fyrir 29. mars 2019 (umsóknum um ný markaðsleyfi, breytingar og endurnýjanir) þar sem UK er RMS
- **Koma í veg fyrir að skortur verði á lyfjum fyrir menn og dýr!**

Staða á Íslandi

Staðan á Íslandi

- CP lyf - EMA fylgist með framgangi.
- Lyf sem Ísland er RMS fyrir - Lyfjastofnun
- Hrein landsmarkaðsleyfi á Íslandi - Lyfjastofnun
- CMS markaðsleyfi á Íslandi - viðkomandi RMS og MLH

- Geislavirk lyf - UK?
- Könnun á stöðunni?

- Birgðastaða – biðlistar - hömstrun


KEEP
CALM
AND
CARRY
ON

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Brexit - hvað næst?

Fylgstu með

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