



**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



Brussels, 22 November 2018  
(OR. en)

XT 21095/18

BXT 111  
CO EUR-PREP 54

**NOTE**

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

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Delegations<sup>1</sup> will find in the Annex the Political declaration setting out the framework for the future relationship between the European Union and the United Kingdom. This declaration has been agreed at negotiators' level and agreed in principle at political level, subject to the endorsement of Leaders.

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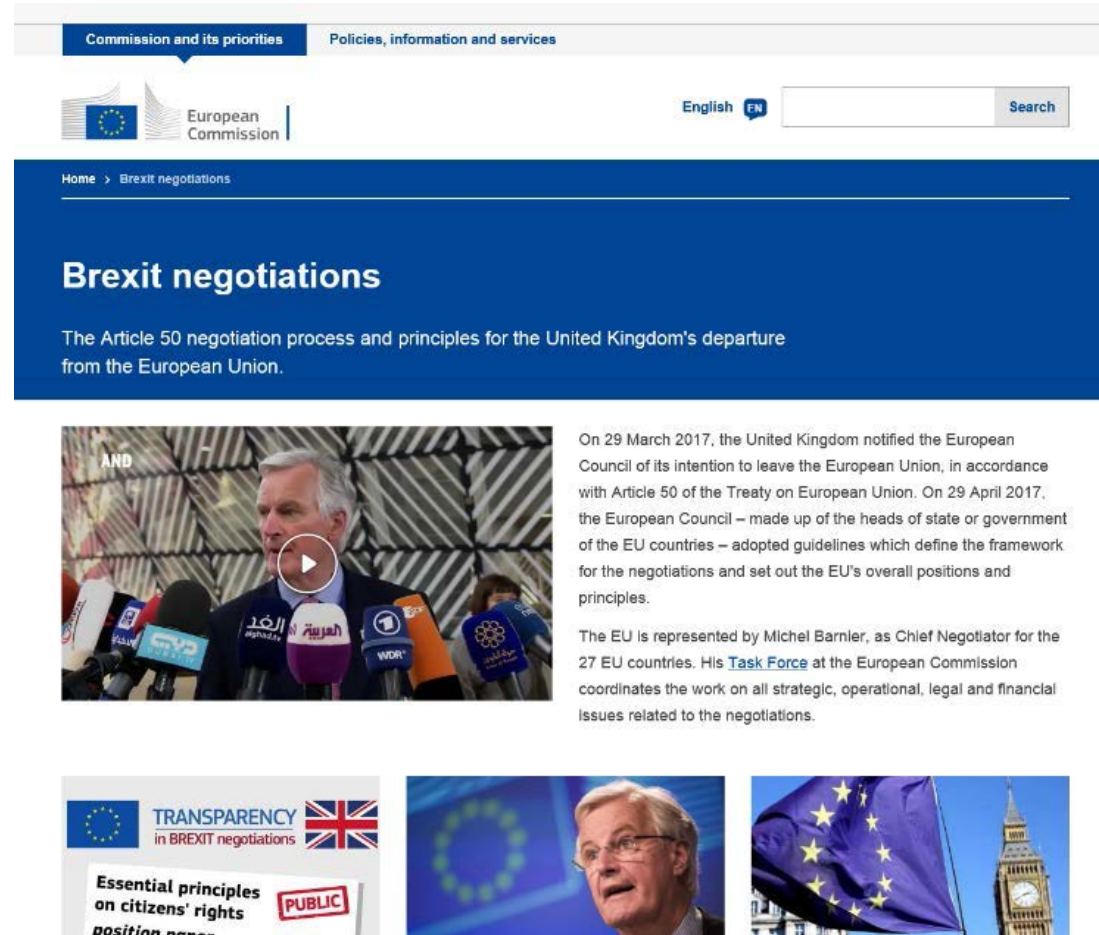
<sup>1</sup> Following a notification under Article 50 TEU, the member of the European Council or of the Council representing the withdrawing Member State shall not participate in the discussions of the European Council or Council or in decisions concerning it.

Hvar eru upplýsingar um áhrif Brexit?

# Framkvæmdastjórnin

[https://ec.europa.eu/commission/brexit-negotiations\\_en](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



The screenshot shows the European Commission website page for Brexit negotiations. The page header includes "Commission and its priorities" and "Policies, information and services". The European Commission logo is visible, along with a search bar and a language selector set to "English". The main heading is "Brexit negotiations", with a sub-heading: "The Article 50 negotiation process and principles for the United Kingdom's departure from the European Union." Below this is a video player showing a man speaking at a press conference. To the right of the video is a text block: "On 29 March 2017, the United Kingdom notified the European Council of its intention to leave the European Union, in accordance with Article 50 of the Treaty on European Union. On 29 April 2017, the European Council – made up of the heads of state or government of the EU countries – adopted guidelines which define the framework for the negotiations and set out the EU's overall positions and principles. The EU is represented by Michel Barnier, as Chief Negotiator for the 27 EU countries. His Task Force at the European Commission coordinates the work on all strategic, operational, legal and financial issues related to the negotiations." Below the video and text are three smaller images: a "TRANSPARENCY in BREXIT negotiations" sign, a man speaking, and the European Union flag.

<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 [Share](#)

### Table of contents

- [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
	<ul style="list-style-type: none"> <li>• location of entities, including:               <ul style="list-style-type: none"> <li>• <a href="#">marketing authorisation holders</a> and applicants;</li> <li>• <a href="#">orphan designation holders</a>;</li> </ul> </li> </ul>	

# 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




 RSS | Siter

Navigation: [About HMA](#) | **Human Medicines** | [Veterinary Medicines](#)

You are here: [Home](#) > [Human Medicines](#) > [CMDh](#) > [BREXIT](#)

CMDh

- About CMDh
- Statistics
- Agendas and Minutes
- Press Releases
- BREXIT**
- Procedural Guidance
- CMDh-Referrals
- Product Information
- Advice from CMDh
- Templates



- **Notice to marketing authorisation holders of national authorised medicinal products for human use** (June 2018) [*Track version*]
- **Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to national authorised medicinal products for human use** (June 2018) [*Track version*]
- **Practical guidance for procedures related to Brexit for medicinal products for human use approved via MRP/DCP** (December 2018)[*Track version*]
- **National information on MAH transfers** (January 2019)

# 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>

The screenshot shows the GOV.UK website interface. At the top, there is a search bar and a navigation menu. Below the navigation, there is a blue banner with the text 'Tell us what you think of GOV.UK' and a 'Close' button. The main content area features a breadcrumb trail: 'Home > How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal'. Below this is the logo for the Department of Health & Social Care. The main heading is 'Guidance: How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal', updated on 14 September 2018. The page content is divided into two columns. The left column contains a 'Contents' section with links for 'Purpose', 'Before 29 March 2019', 'After 29 March 2019 if there's no deal', 'Implications', and 'More information'. The right column contains the main text, which discusses the 'no deal' scenario and the government's preparations for it.

GOV.UK Search

Tell us what you think of GOV.UK [Close](#)  
Take a short survey to give us your feedback

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

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 place in the event of a 'no deal' outcome. Rather it is about ensuring our plans are in place in the event of a 'no deal' outcome.

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**



**Lyfjastofnun**

Icelandic Medicines Agency

Brexit - hvað næst?

**Fylgstu með**

[www.lyfjastofnun.is](http://www.lyfjastofnun.is) | [twitter.com/Lyfjastofnun](https://twitter.com/Lyfjastofnun) | [facebook.com/Lyfjastofnun](https://facebook.com/Lyfjastofnun)

