

Brexit - status

Informasjonsmøte Legemiddelverket 27.11.18

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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

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

Delegations¹ 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 the 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.

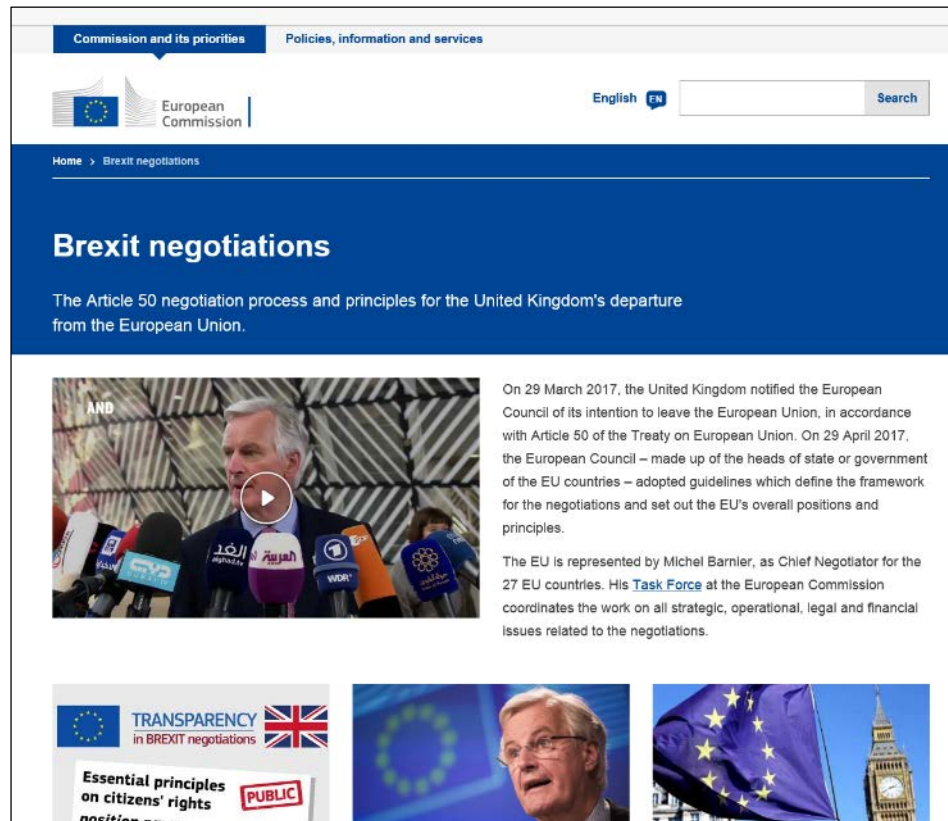
**Hvor finnes relevant informasjon og
veiledning om Brexit og konsekvenser
for legemidler?**

Utviklingen på europeisk nivå

- EU kommisjonens nettside

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

- Info om forhandlingene
- Utkast avtale 14.11.2018
- Overgangsordning til 31.12.2020 – eller lengre?
- Forklarende Q&As
- Pressemeldinger



The screenshot shows the top part of the European Commission website. At the top, there are navigation links for "Commission and its priorities" and "Policies, information and services". Below this is the European Commission logo and the text "European Commission". To the right, there is a language selector set to "English" and a search bar. The main heading of the page 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 the text is a video player showing a man speaking at a press conference. To the right of the video is a text block starting with "On 29 March 2017, the United Kingdom notified the European Council of its intention to leave the European Union...". Below the video and text are three smaller images: one with the text "TRANSPARENCY in BREXIT negotiations" and "Essential principles on citizens' rights", another showing a man speaking, and a third showing the European Union flag and Big Ben.

Informasjon fra EMA

- Brexit nettside med veiledning for industri for CP produkter/prosedyrer
- <https://www.ema.europa.eu/en/about-us/uks-withdrawal-eu/brexit-related-guidance-companies>
- EU kommisjonen/EMA Q&As, EMA praktisk guide
- Referat fra møter med interessenter “stakeholder meetings”
- Pressemeldinger
- Resultater industri-undersøkelse Brexit forberedelse
- Redistribusjon av (co)rapportørskap i CP er ferdigstilt

Informasjon fra CMDh og CMDv

- Veiledning til industrien for nasjonalt godkjente produkter
 - [CMDh](http://www.hma.eu/535.html) <http://www.hma.eu/535.html>
 - [CMDv](http://www.hma.eu/542.html) <http://www.hma.eu/542.html>
- Regulatoriske Q&As for nasjonalt godkjente produkter
- Praktisk veiledning for prosedyrer relatert til Brexit
- Templat for overføring av RMS

Informasjon fra UK

- Brexit nettside:
 - <https://www.gov.uk/government/brexit>
- Informasjon i tilfelle “no deal”:
 - <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>
- Informasjon i tilfelle avtale/overgangsperiode:
 - <https://www.gov.uk/government/publications/implementation-period-what-it-means-for-the-life-sciences-sector>

The screenshot shows the UK Government website (GOV.UK) with a search bar and a navigation menu. The main content area features a blue header with the title "Guidance: How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal" and a sub-header "Updated 14 September 2018". Below the header, there is a table of contents with links to "Contents", "Purpose", "Before 29 March 2019", "After 29 March 2019 if there's no deal", "Implications", and "More information". The main text area contains three paragraphs of text, each starting with a bolded heading: "A scenario in which the UK leaves the EU without agreement...", "Negotiations are progressing well and both we and the EU continue to work hard to seek a positive deal...", and "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...".

GOV.UK

Search

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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

**Følg med for oppdateringer
og ny informasjon!**

Krav om lokalisering innen EØS

- MT-innehaver og MT-søker
- RMS
- Sponsor for «orphan designation»
- QPPV og PSMF (Pharmacovigilance System Master File)
- SME (for tilgang til fordelene ved programmet)
- Batch testing og frigivelse av produkt
- «Supervisory authority» GMP
- UK blir tredjeland med hensyn til tilvirkning av aktiv substans og import av ferdig preparat

Hva må MT-innehavere gjøre

- Fortsatt forberede seg på «hard Brexit», dvs. ingen overgangsavtale med UK
- Undersøke om Brexit vil kunne påvirke tilgang av legemidler
 - F.eks. må batch frigivelse og testing av legemidler skje i EU/EØS
- Informere myndighetene ved potensiell fare for leveransedyktigheten grunnet Brexit
- For produkter med UK som RMS: avtale ny RMS og overføre
 - Kontakte CMDh/v ved vanskeligheter med å finne ny RMS

Hva må MT-innehavere gjøre

- Tilpasse prosesser og ta høyde for endringer som er nødvendig for at MT'ene skal være valide og legemidlene tilgjengelige etter Brexit
- Sende inn endringssøknader som nødvendig grunnet Brexit
 - Diskutere med de nasjonale myndighetene tidspunkt for innsendelse av endringer
- Sørg for å ferdigstille pågående prosedyrer (nye MT-søknader, endringer, fornyelser) der UK er RMS innen 29. mars 2019
 - OBS! Avslutte clock stops så fort som mulig
- Unngå legemiddelmangel til mennesker og dyr

CMDh monitorering av Brexit forberedelser

Brexit relaterte RMS overføringer status nov. 2018

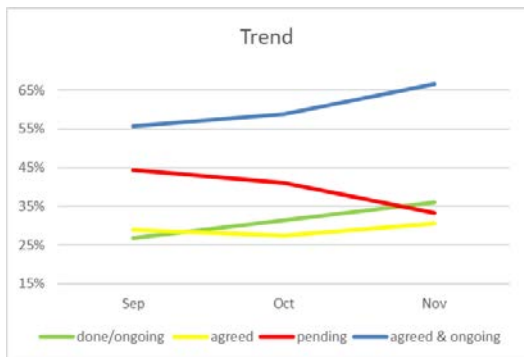
UK PROCEDURES TO BE REDISTRIBUTED WITHIN THE EEA-29
(Pharmaceutical forms and strengths in a MA counted as one)
(HUMAN MP ONLY: 2364)

RMS switch pending*
789
33%

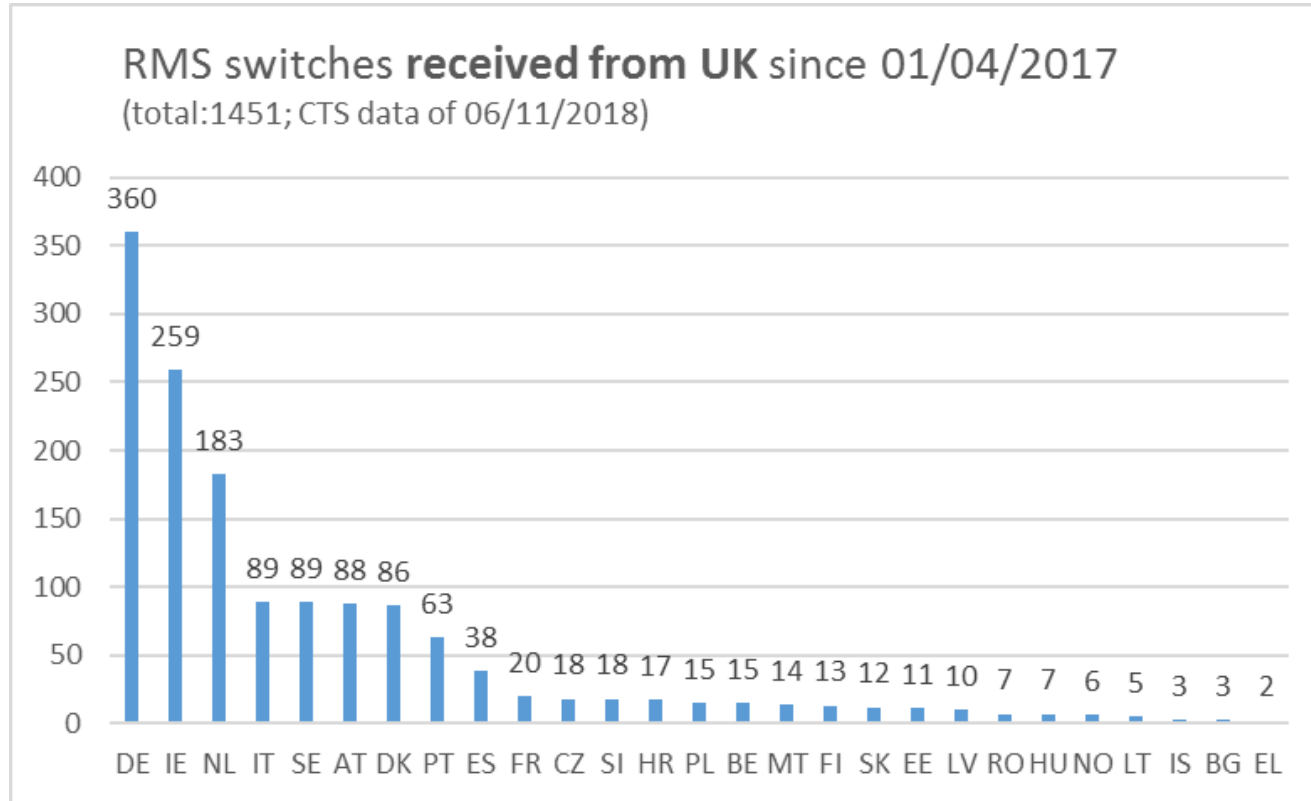
RMS switch done/ongoing in
CTS (after 01/04/2018)
853
36%

RMS switch agreed in
Brexit tool
722
31%

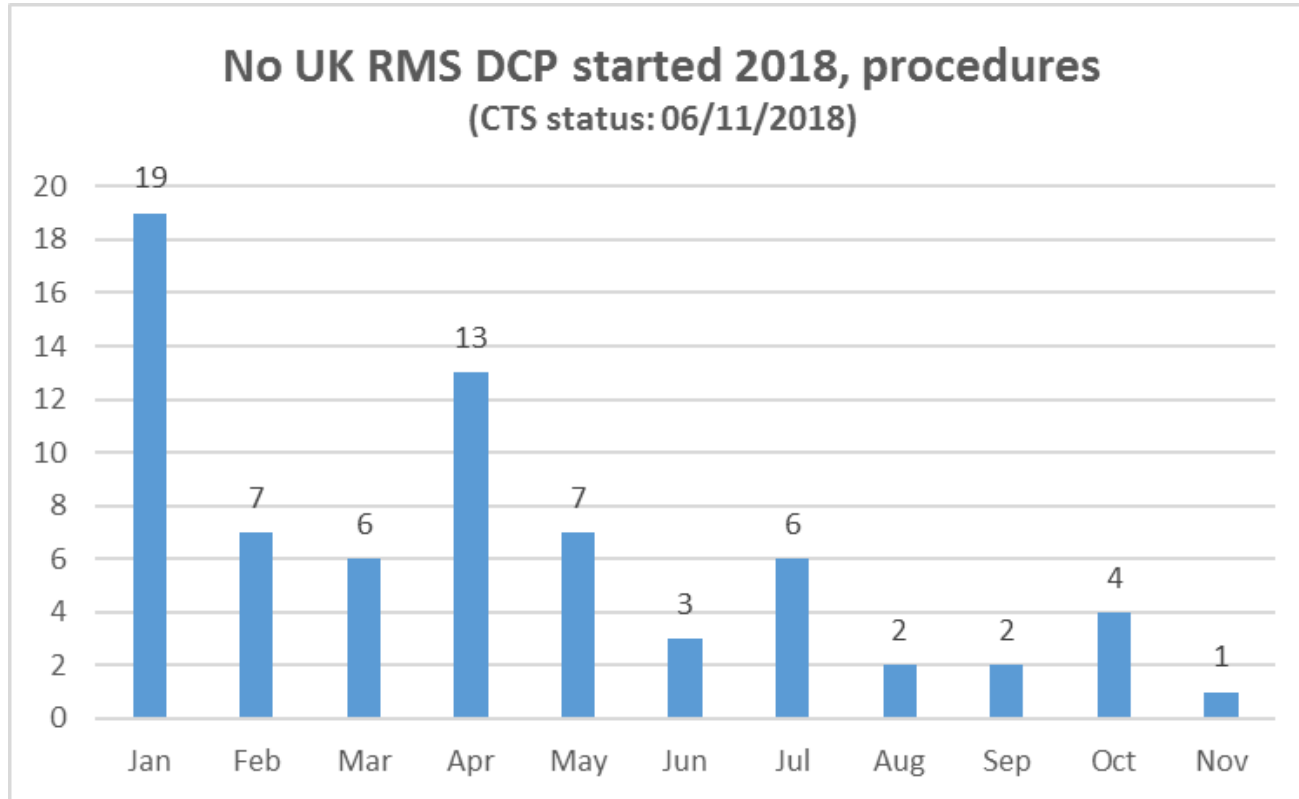
*including
12 (0,5%) recorded 'Requests' and
20 (0,8%) 'Rejections by CMS'
following MAH contact



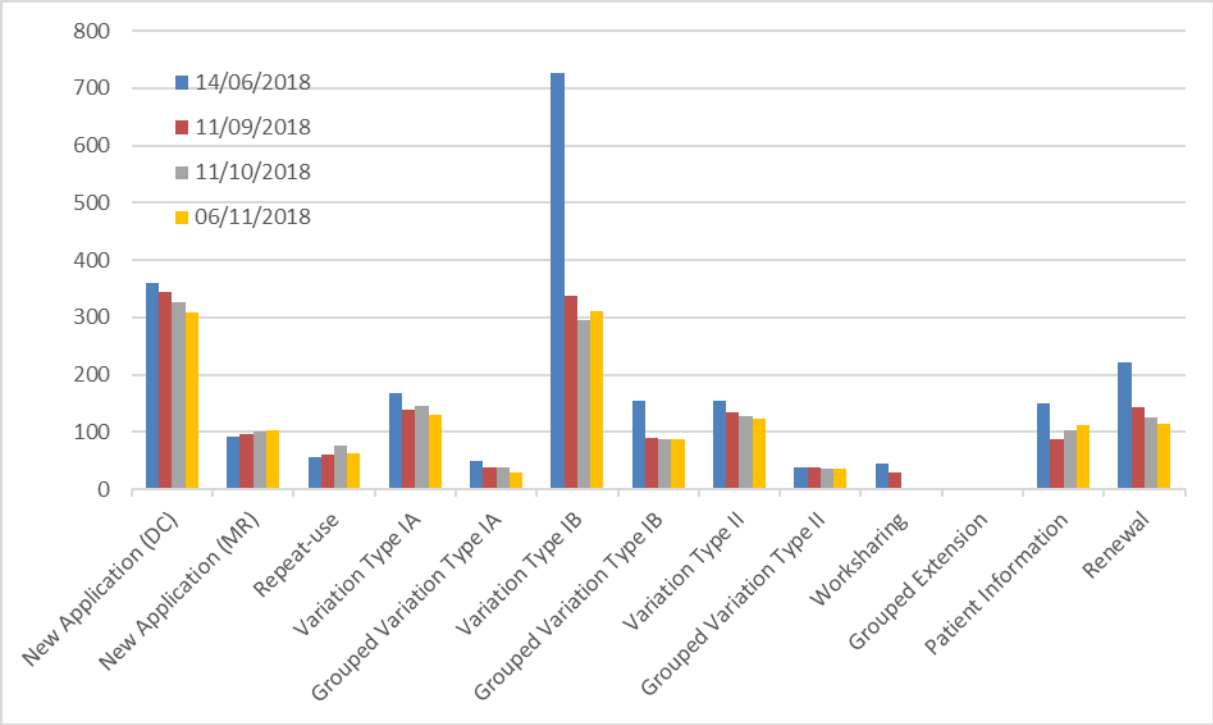
RMS overføringer mottatt fra UK, per land



DCP prosedyrer med UK RMS startet i 2018



Pågående prosedyrer med UK RMS, fordelt per type





KEEP
CALM

and

HUG ME

Følg oss



@legemiddelinfo



legemiddelverket

[legemiddelverket.no](https://www.legemiddelverket.no)



Statens
legemiddelverk