News story: Making a success of Brexit

Following the outcome of the EU referendum, the Medicines and Healthcare products Regulatory Agency (MHRA) is working closely with the Government to analyse the best options and opportunities available for the safe and effective regulation of medicines and medical devices in the UK.

While negotiations continue, the UK remains a full and active member of the EU, with all the rights and obligations of EU membership firmly in place. Working with our partners, stakeholders and customers, our focus remains: protecting health and improving lives.

Medicines regulation

Playing a full, active role in European regulatory procedures for medicines remains a priority. We contribute significantly in both the centralised and decentralised regulatory procedures, including new rapporteur and reference member state (RMS) appointments, and maintain our programmes for implementing EU legislation as required by our obligations as a Member State. We are also fully engaged in European and national scientific advice services and in delivering our EU inspection-related duties.

Devices regulation

Our role in regulating medical devices and in vitro diagnostic (IVD) devices remains integral. We oversee the essential work of the five UK Notified Bodies; together they are responsible for assessing the majority of devices currently placed on the EU market. Our preparations to implement proposed new Regulations for Medical Devices and IVDs continue.

Vigilance and market surveillance

We maintain our role in vigilance, market surveillance and taking direct action, where needed, to protect patients and public health, and we continue to co-ordinate with other Competent Authorities, across Europe and internationally, in these and other areas.

Future regulatory partnership

On 4 July the UK Government gave a clear, public statement of its desire to retain a close working partnership in respect of medicines regulation after the UK leaves the EU, in the interests of public health and safety. The statement, published in the Financial Times, by the Secretary of State for Health and Secretary of State for Business, Energy and Industrial Strategy laid out the three principles which will underpin the development of a post-Brexit regulatory system for medicines and devices: patients should not be disadvantaged; innovators should be able to access the UK market as quickly and simply as possible; and we will continue to play a leading role in both Europe and the world in promoting public health.

These principles and the government's position were developed further in a <u>speech by the Parliamentary Under Secretary of State at the Department of</u> <u>Health, Lord O'Shaughnessy</u>, at the BIA/MHRA conference in London on 14 July.

The commitment to continuing the close working relationship with our European partners with respect of medicines regulation and protecting public health globally is also reiterated on page 14 of the <u>Governments Collaboration on</u> <u>science and innovation 'A Future Partnership Paper'</u> published in September 2017.

More broadly, as part of the <u>guidelines</u> adopted for the second phase of the negotiations at the European Council meeting on December 15, the European Council reconfirmed it's desire to establish a close partnership between the UK and EU.

EMA/EU & CMDh notices to Marketing Authorisation Holders

We are aware of the recent notices to Marketing Authorisation Holders issued by the EMA/EU-27 and CMDh advising of preparations MA holders may want to consider ahead of the UK's exit from the EU.

Until the exit negotiations are concluded, the UK remains a full member of the EU and all the rights and obligations of EU membership remain in force. We therefore continue to play a full role in the network and to undertake our work as a Reference Member State (RMS) in the decentralised procedure, and as (co-) rapporteur in the centralised procedure. If, however you do want to consider preparation for any potential changes to marketing authorisation or RMS, please see the information provided by the EMA and the HMA.

Whatever the outcome of the negotiation we will continue to collaborate with all involved to deliver the current speed of authorisations, access to new and innovative medicines and devices and to continue to ensure the quality, safety and efficacy of all medicines and devices, to safeguard an uninterrupted level of public health protection.

On 23 August 2018 the government published guidance for businesses and citizens on how to prepare for exiting the EU if there's no deal.

This guidance is in the form of a series of technical notices, a number of which relate directly to the work of the Agency:

A further 3 technical notices are also related to the work of the Agency and the Department of Health and Social Care (DHSC):

<u>Guidance for marketing authorisation holders</u> in the event of a no-deal Brexit has been published by DHSC.

We have also published our <u>letter to industry</u>, and accompanying guidance, covering the conversion of existing approved Community Marketing

Authorisations to UK Marketing Authorisations (MAs) and a <u>letter providing</u> <u>Product Licence numbers and the actions</u> that companies are asked to take.

<u>A letter to suppliers of medical devices and clinical consumables</u> about contingency planning for a no-deal Brexit has been published by DHSC.

In January 2019 we published information on <u>how to make regulatory medicines</u> <u>submissions to the MHRA</u> if the UK leaves the EU with no deal.

MHRA consultation on EU exit no-deal legislative proposals

We ran a <u>consultation</u> on the regulatory processes which would have to be modified in the event of the UK not securing a deal with the EU after the UK's exit, with no Implementation Period.

We responded to this consultation, in the form of a <u>further guidance note</u> on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal, on 3 January 2019.

Customers, partners and stakeholders approaching MHRA continue to have access to our internationally recognised expertise and we maintain the highest quality services. For further information, please get in touch with your usual contact points in the Agency.

Essential maintenance to Companies House online services

1. 17 November 2022

There will be maintenance work taking place, which may affect Companies House services, between Saturday 19 November and Monday 21 November.

2. 15 November 2022

Maintenance window scheduled for Saturday 19 November from 8am to 10pm may cause disruption to online services

3. 8 November 2022

New maintenance window between 8pm and 9pm this evening (Tuesday 8 November)

4. 5 October 2022

Maintenance work will affect our online services from Friday 14 October to Monday 17 October.

5. 8 September 2022

Essential maintenance to our web services

6. 7 September 2022

Potential disruption because of essential maintenance work.

7. 8 August 2022

Changed date

8. 25 July 2022

Edited to change date of maintenance work to 1 August.

9. 13 July 2022

Maintenance work will affect our online services on Saturday 16 July.

10. 20 June 2022

Maintenance on Saturday 25 June and Sunday 26 June 2022.

11. 13 June 2022

Maintenance work will affect our online services on Saturday 18 June and Sunday 19 June.

12. 6 June 2022

Weekend maintenance work will affect our online services on 11-12 June and 18-19 June 2022.

13. 30 May 2022

Maintenance will affect our online services on Saturday 4 June 2022.

14. 19 May 2022

Disruption to Companies House online services from 10am to 2pm on Saturday 21 May 2022.

15. 10 May 2022

Added Find and update company information to list of affected services.

16. 9 May 2022

All Companies House online services will be unavailable from 8am to 8pm on Sunday 15 May 2022.

17. 4 May 2022

Maintenance will affect our online services on Saturday 7 May.

18. 8 April 2022

Maintenance will affect our online services on Sunday 24 April.

19. 23 March 2022

Maintenance will affect our online services on Saturday 26 March.

20. 7 March 2022

Maintenance will affect our online services on Saturday 12 March.

21. 22 February 2022

Maintenance will affect our online services on Thursday 24 February.

22. 17 February 2022

Our Report a PSC discrepancy and Apply to strike off and dissolve a company services will be unavailable on Sunday 20 February.

23. 14 February 2022

Maintenance will affect our online services on Sunday 20 February.

24. 8 February 2022

Maintenance will affect our online services on Thursday 10 February.

25. 28 January 2022

Maintenance will affect our online services on Wednesday 2 February.

26. 13 January 2022

Maintenance will affect our online services on Saturday 22 January.

27. 1 December 2021

Maintenance will affect our online services between 7am and 9am on Saturday 4 December.

28. 14 November 2021

Our Webfiling service and XML Gateway will not be available for about 2 hours from 8:30pm on Sunday 14 November.

29. 8 November 2021

Maintenance will affect our online services from Friday 12 November to Monday 15 November.

30. 3 November 2021

Maintenance scheduled for Saturday 6 November has been cancelled. You may experience disruption when using our online services from 8am to midday on Sunday 7 November.

31. 2 November 2021

Maintenance will affect our online services on Saturday 6 and Sunday 7 November.

32. 20 October 2021

Maintenance may affect our online services from 7am to 5pm on Saturday 23 October.

33. 11 October 2021

Maintenance may affect our online services from 7am to midday on Saturday 16 October.

34. 28 September 2021

Maintenance may affect our online services from 10am to 1pm on Saturday 9 October.

35. 22 September 2021

Maintenance on Saturday 25 September will affect Companies House Direct (CHD).

36. 6 September 2021

There may be disruption to our online services from 3am to 4am on Sunday 12 September.

37. 3 August 2021

Maintenance will affect our online services from 9am to 1pm on Saturday 7 August.

38. 2 July 2021

Maintenance will affect our online services on Saturday 10 July.

39. 24 June 2021

There may be some disruption to our online payment services from 3am to 4am on Sunday 27 June. Customers may experience disruption of up to 15 minutes when attempting to make payment on our online services during this period.

40. 20 May 2021

There may be disruption to some of our online services from 8pm on Monday 24 May to 6am on Tuesday 25 May.

41. 12 May 2021

There may be disruption to some of our online services from 10pm on Monday 17 May to 4am on Tuesday 18 May.

42. 11 May 2021

Maintenance will affect some of our online services from 8am to 4pm on Saturday 15 May, and 8am to 4pm on Sunday 16 May.

43. 6 May 2021

Maintenance may affect some of our online services from 8pm on Saturday 8 May to 6am on Sunday 9 May.

44. 1 April 2021

Maintenance will affect our online services from 8am to 4pm on Saturday 17 April.

45. 25 March 2021

Our WebFiling service and XML gateway (software filing and search) may not be available from 8pm on Friday 26 March to 6am on Saturday 27 March, and from 8pm on Saturday 27 March to 6am on Sunday 28 March.

46. 22 March 2021

Maintenance on Wednesday 24 March will affect our online filing and software services.

47. 18 March 2021

Updated as scheduled maintainance has been cancelled

48. 15 March 2021

Maintenance will affect our online filing and software services on Saturday 20 March.

49. 1 March 2021

Online filing and XML gateway will not be available on Saturday 6 March.

50. 17 February 2021

Possible disruption to our online and software filing services between 8am and 10am on Saturday 20 February.

51. 8 February 2021

Moving our XML database to the cloud on Saturday 13 February as part of the cloud migration work.

52. 2 February 2021

Maintenance on Sunday 7 February will affect Companies House service (CHS).

53. 18 January 2021

Maintenance on Saturday 23 January will affect confirmation receipts for online filing.

54. 14 January 2021

Maintenance scheduled for Saturday 16 January cancelled.

55. 11 January 2021

Maintenance on Saturday 23 January from 8am to 8pm will delay confirmation receipts for online filing.

56. 7 January 2021

Maintenance may affect our online services on Saturday 9 January.

57. 22 December 2020

Maintenance may affect our online services from 7pm on Thursday 31 December to 7am on Friday 1 January 2021.

58. 9 December 2020

Maintenance from 8am to 2pm on Saturday 12 December.

59. 8 October 2020

Maintenance from 7am to 12pm on Saturday 10 October.

60. 30 September 2020

Maintenance to Companies House Service (CHS) from 9am to 3pm on Saturday 3 October.

61. 11 June 2020

Maintenance work will affect our online services from 8am to 12pm on Sunday 14 June.

62. 27 May 2020

Maintenance cancelled for Sunday 31 May.

63. 26 May 2020

Planned maintenance to Companies House Service at 8am on Sunday 31 May.

64. 8 April 2020

Maintenance to the online extensions service at 8pm on Wednesday 8 April.

65. 3 April 2020

Maintenance to the online extensions service at 9am on Sunday 5 April.

66. 2 April 2020

Maintenance to extensions service at 8pm on Thursday 2 April.

67. 1 April 2020

Maintenance to extensions service at 8pm on Wednesday 1 April.

68. 5 March 2020

Maintenance planned for Saturday 7 March and Sunday 8 March.

69. 11 November 2019

Maintenance work to CHS on Thursday 14 November.

70. 5 November 2019

Maintenance planned for Saturday 9 November.

71. 31 October 2019

Maintenance to CHS on Monday 4 November.

72. 16 October 2019

Maintenance for Wednesday 16 October cancelled.

73. 11 October 2019

Maintenance on Wednesday 16 October.

74. 3 October 2019

Maintenance for Saturday 5 October cancelled.

75. 1 October 2019

Added translation

76. 30 September 2019

Planned online maintenance on Saturday 5 October.

77. 31 July 2019

Maintenance on Saturday 3 August.

78. 1 May 2019

Maintenance on Saturday 4 May 2019.

79. 10 April 2019

Maintenance on Friday 12 April and Saturday 13 April.

80. 25 March 2019

Maintenance extended to 7am Wednesday 27 March.

81. 21 March 2019

Maintenance on Monday 25 March to Tuesday 26 March.

82. 21 February 2019

Maintenance on Saturday 23 February 2019.

83. 29 January 2019

Maintenance on Sun 3 Feb and Sat 16 Feb.

84. 22 January 2019

Maintenance on Saturday 16 February.

85. 16 January 2019

Maintenance to our online strike off service from 19 to 20 January.

86. 11 January 2019

Maintenance for Sunday 13 January cancelled.

87. 9 January 2019

Maintenance to our services on Sunday 13 January 2019.

88. 28 November 2018

Maintenance on Saturday 1 December.

89. 19 November 2018

Maintenance on Wednesday 21 November.

90. 12 November 2018

Maintenance on Wednesday 14 November.

91. 7 November 2018

E-billing service unavailable from 9am to 1pm on Sunday 11 November.

92. 5 November 2018

Maintenance on Saturday 10 November and Sunday 11 November.

93. 2 November 2018

Maintenance scheduled for Saturday 10 November and Sunday 11 November.

94. 26 October 2018

Maintenance planned for Saturday 3 November 2018.

95. 26 October 2018

Issue with our phone lines.

96. 26 October 2018

Maintenance planned for Saturday 3 November 2018.

97. 21 September 2018

Essential maintenance planned for Tuesday 25 September.

98. 22 August 2018

Essential upgrades to our incorporation services on 8 September 2018.

99. 5 August 2018

Issues with WebFiling, CHD and WebCHeck

100. 1 August 2018

Maintenance window

101. 23 July 2018

Maintenance window

102. 19 July 2018

Essential maintenance

103. 27 June 2018

Essential maintenance notice

104. 6 March 2018

Maintenance message

105. 4 March 2018

Updated as office reopen.

106. 2 March 2018

Update to our opening times.

107. 1 March 2018

Updated to include press contact details.

108. 1 March 2018

Companies House offices closed due to weather.

109. 7 February 2018

CHS issues.

110. 23 January 2018

Notice about issues with our finance systems.

111. 8 January 2018

CHS issues resolved

112. 8 January 2018

Problems with CHS

113. 18 December 2017

Possible disruption to Companies House Service

114. 1 December 2017

Power issues now resolved.

115. 1 December 2017

Update.

116. 1 December 2017

Issue at our Edinburgh office.

117. 9 November 2017

Maintenance planned for 11 November.

118. 3 November 2017

Maintenance cancelled.

119. 30 October 2017

Planned maintenance 4 November.

120. 30 October 2017

Maintenance planned for 4 November.

121. 23 October 2017

Alert about service maintenance.

122. 11 October 2017

Essential maintenance message

123. 25 September 2017

Additional maintenance required

124. 18 September 2017

Update to article

125. 21 June 2017

Planned maintenance 25 June 2017

126. 18 April 2017

Planned maintenance successfully completed and all services back on line.

127. 13 April 2017

CHS now not available from 4pm on 13 April

128. 11 April 2017

Added note that Follow won't be available during the maintenance.

129. 20 March 2017

Essential maintenance from 11:59pm on Thursday 13 April to 7am on Tuesday 18 April.

130. 6 December 2016

Planned maintenance completed successfully.

131. 30 November 2016

Maintenance planned between Friday 2 December to Sunday 4 December

132. 11 October 2016

Essential online maintenance between 7am-8pm Saturday 15 October 2016

133. 18 April 2016

Planned maintenance message removed.

134. 4 April 2016

First published.

Update: air strikes against Daesh

Published 29 January 2016 Last updated 13 October 2022 <u>+ show all updates</u>

1. 13 October 2022

Update: RAF Reaper strike on Daesh terrorist in Iraq

2. 2 July 2022

Update: RAF Reaper strike on Daesh terrorists in Iraq

3. 16 December 2021

Updated strike statement

4. 27 November 2021

Updated on Saturday 27 November.

5. 20 September 2021

Updated strike statement

6. 25 June 2021

Added content under useful information heading.

7. 17 May 2021

Updated Strike Statement

8. 8 April 2021

Updated strike activity.

9. 23 March 2021

Update on latest strikes

10. 15 March 2021

Updating strike statement

11. 18 February 2021

Updated strike statement

12. 30 January 2021

Updated strike statement

13. 14 October 2020

Updated air strikes

14. 12 September 2020

We are updating with new strikes information

15. 15 July 2020

Updated strike statement

16. 29 May 2020

Updated strikes

17. 5 May 2020

Updated strikes

18. 25 April 2020

Updated detail on airstrikes against Daesh

19. 27 September 2019

Updated strike

20. 16 September 2019

Updated strikes

21. 13 August 2019

Updated strikes

22. 1 July 2019

New strikes

23. 29 April 2019

Updated strikes

24. 25 March 2019

Updated strikes

25. 4 March 2019

Update to strikes

26. 25 February 2019

Updated strikes

27. 22 February 2019

Fresh strikes

28. 10 January 2019

Updated strikes

29. 20 December 2018

Updated strieks

30. 20 December 2018

Updated with new strikes

31. 26 November 2018

Update

32. 30 October 2018

Updated with new strikes.

33. 16 October 2018

Updated strike statement.

34. 3 September 2018

Updated strikes

35. 3 August 2018

Update

36. 26 June 2018

Update to strikes

37. 15 June 2018

Update to strikes

38. 25 May 2018

Updated Friday 25 May 2018

39. 9 May 2018

Update on strikes

40. 8 May 2018

Update to strike.

41. 4 April 2018

Update to strikes

42. 13 February 2018

Updated 13 February 2018

43. 6 February 2018

reformatted

44. 6 February 2018

Reformatted

45. 23 January 2018

Updated 23 January 2018

46. 15 January 2018

Update to strike statement

47. 8 January 2018

Update.

48. 11 December 2017

Updated 11 December 2017

49. 28 November 2017

Update to strikes

50. 14 November 2017

Update to strikes

51. 10 October 2017

Update to strike statement

52. 30 September 2017

Update to strike statement

53. 31 August 2017

update to strike statement

54. 22 August 2017

Update to strike statement

55. 8 August 2017

Update to strike statement

56. 31 July 2017

Update to strike statement.

57. 31 July 2017

Update to strike statement.

58. 31 July 2017

Update to statement

59. 31 July 2017

Update to strike statement.

60. 25 July 2017

Update to strike statement.

61. 17 July 2017

Updated strike statement.

62. 13 July 2017

Update to strike statement.

63. 10 July 2017

Updated strike statement.

64. 6 July 2017

update

- 65. 6 July 2017 update
- 66. 3 July 2017

update

67. 30 June 2017

update

68. 12 June 2017

update

69. 6 June 2017

Strike update

70. 30 May 2017

Strike update

71. 22 May 2017

Strike update.

72. 16 May 2017

update

73. 9 May 2017

update

- 74. 2 May 2017 update
- 75. 24 April 2017

update

- 76. 19 April 2017 update
- 77. 10 April 2017

update

78. 4 April 2017

update

- 79. 28 March 2017 update
- 80. 28 March 2017

update

81. 21 March 2017

update

82. 13 March 2017

update

83. 9 March 2017

update

84. 6 March 2017

update

- 85. 28 February 2017 update
- 86. 23 February 2017

Latest strike update

87. 16 February 2017

Latest strike update

- 88. 11 February 2017
 update
- 89. 2 February 2017
 update
- 90. 30 January 2017 update
- 91. 24 January 2017

update

- 92. 20 January 2017 update
- 93. 17 January 2017 update
- 94. 12 January 2017

update

95. 9 January 2017

update

96. 4 January 2017

Latest strike update

97. 3 January 2017

update

98. 2 January 2017

update

99. 2 January 2017

latest update

100. 28 December 2016

Updated strike update.

101. 22 December 2016

update

102. 15 December 2016

Latest strike update.

103. 12 December 2016

Update

104. 5 December 2016

Updated with video.

105. 5 December 2016

Updated information on air operations against Daesh.

106. 28 November 2016

update

107. 25 November 2016

update

108. 24 November 2016

Video added

109. 21 November 2016

update

110. 17 November 2016

update

111. 14 November 2016

Update

112. 10 November 2016

update

- 113. 7 November 2016 Update
- 114. 2 November 2016

Update

- 115. 28 October 2016 update
- 116. 25 October 2016 Update
- 117. 21 October 2016 update
- 118. 21 October 2016 change to caption
- 119. 19 October 2016

Update

- 120. 17 October 2016 update
- 121. 10 October 2016

Update

122. 6 October 2016

update

123. 6 October 2016

updated

124. 6 October 2016

update

125. 3 October 2016

Update

126. 3 October 2016

Update

127. 28 September 2016

Update

128. 23 September 2016

Amended to reflect latest strike update.

129. 14 September 2016

Amended to provide the most recent update.

130. 7 September 2016

update

131. 2 September 2016

Operational update

132. 26 August 2016

Updated strike statement

133. 22 August 2016

Operational update

134. 12 August 2016

update

135. 8 August 2016

Strike update

136. 3 August 2016

update

137. 25 July 2016

Strike update

138. 20 July 2016

Update

139. 14 July 2016

Operational update.

140. 11 July 2016

Strike update

141. 7 July 2016

Strike update

142. 5 July 2016

Operational update.

143. 30 June 2016

Operational update.

144. 27 June 2016

Operational update.

145. 22 June 2016

Operational update.

146. 16 June 2016

Operational update.

147. 13 June 2016

Operational update

148. 9 June 2016

Operational update.

149. 6 June 2016

Operational update

150. 2 June 2016

Operational update

151. 31 May 2016

Operational update

152. 24 May 2016

Operational update.

153. 19 May 2016

Operational update

154. 9 May 2016

Operational update

155. 4 May 2016

Operational update.

156. 26 April 2016

Operational update.

157. 19 April 2016

Operational update

158. 14 April 2016

Operational update

159. 8 April 2016

Operational update.

160. 4 April 2016

Operational update

161. 30 March 2016

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162. 22 March 2016

Operational update

163. 15 March 2016

Operational update

164. 11 March 2016

Operational update.

165. 7 March 2016

Operational update

166. 1 March 2016

Operational update

167. 23 February 2016

Operational update

168. 19 February 2016

Operational Update

169. 15 February 2016

Operational update

170. 2 February 2016

Operational update

171. 29 January 2016

First published.

<u>Travel and health advice for Hajj</u> <u>pilgrims</u>

Published 1 September 2015 Last updated 22 July 2019 <u>+ show all updates</u>

- 1. 22 July 2019 updated link
- 2. 25 June 2019 updated with latest information including a link to Saudi government guidance
- 3. 23 July 2018 updated the attachments for Hajj2018
- 4. 1 September 2015 First published.

<u>News story: Welcome to our new MHRA</u> <u>website</u>

Medicines & Healthcare products Regulatory Agency What the Medicines and Healthcare products Regulatory Agency is doing

Latest from the Medicines and Healthcare products Regulatory Agency

What the Medicines and Healthcare products Regulatory Agency does

Documents

Our management



Dr June Raine

Director of Vigilance and Risk Management of Medicines



<u>John Quinn</u>

Director of Transformation and Chief Digital and Information Officer

Contact MHRA

Make an FOI request

- 1. Read about the Freedom of Information (FOI) Act and how to make a request.
- 2. Check <u>our previous releases</u> to see if we've already answered your question.
- 3. Make a new request by contacting us using the details below.