EU Exit Business Readiness: preparing for a no deal

Q&A on government advice for the consumer healthcare industry

Introduction

This Q&A document sets out a number of frequently asked questions related to government advice on preparing for a no-deal exit from the EU, of relevance to the consumer healthcare industry. This document should be read in conjunction with a full summary of government advice for the consumer healthcare industry, available online here: https://www.pagb.co.uk/content/uploads/2019/10/20191004-PAGB-Business-Readiness-guidance-v0-4.pdf.

It builds on questions raised during two webinars held by PAGB on 10 and 21 October 2019, a recording of which can be accessed here:

https://www.pagb.co.uk/latest-news/webinar-eu-exit/

This document covers the following topics:

Q10: How will medical device labelling look following a no-deal EU Exit?

Q11: Will the new UK Responsible Person role include liability?

Q12: Can the UK Responsible Person be an importer?

Q13: If a manufacturer already has arrangements in place for a UK Responsible Person for their products, do we, as a distributor of these products, also need to have a UK Responsible Person in order to sell them in the UK?

Q14: Will there be labelling changes to reflect the role of the Responsible Person?

Changes to nutrition legislation with regard to food supplements

Q14: What are the key dates and deadlines to be aware of?

Q15: Will food supplement products imported from or exported to the EU need to have health certificates?

Changes to customs authorisations

Q16: Will each additional product imported from the EU to the UK need to be registered with the HMRC as an amendment to current authorisation at the point at which it is imported? Or can they be registered through periodic submissions?

All hyperlinks are current as of 29 October 2019. Advice is based on guidance issued by the Government up to and including 29 October 2019.

Full government guidance is available here: https://www.gov.uk/business-uk-leaving-eu.

If you have any technical questions the Business Support Helpline can be contacted at: enquiries@businesssupporthelpline.org.

For more information, please contact Donna Castle: donna.castle@pagb.co.uk.

PAGB (Proprietary Association of Great Britain)
New Penderel House
283-288 High Holborn
London, WC1V 7HP
www.pagb.co.uk

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Changes to the regulation of medicines

Q1: What are the key dates and deadlines to be aware of?

The EU and the UK Government have agreed to extend the deadline for the UK leaving the EU from 31 October 2019 to 31 January 2020, with an earlier exit permitted if relevant legislative agreements are completed before this time.

Table 1 sets out the relevant deadlines as they are stated within current government guidance, correct as of 29 October 2019. The dates that exist in current guidance but are due to be updated are highlighted in yellow for ease of reference.

Table 1

Day 1 of EU Exit	• Minimum of six weeks additional supply of POM/P medicines to be stockpiled • QPPV should be established in UK – where this is not possible the EU QPPV can **temporarily** assume responsibility in the UK • In respect of manufacturing licence, QP for products manufactured in the UK or directly imported from non-EU/EEA country must be established in the UK • All CAPs automatically become UK MAs • Assurance systems to be in place for companies importing QP-tested and batch released medicines from EU/EEA countries • MHRA takes on functions currently undertaken by the EMA for human medicines on the UK market

4 weeks after exit day	• Where there is not a UK based Marketing Authorisation Holder, companies have four weeks from exit day to put in place:
	  ○ A UK-based contact person accessible to the licensing authority on any matter relating to the MA
	  ○ A UK-based contact person accessible to the licensing authority on any matter relating to the parallel import licence

6 months after exit day	• Deadline by which wholesale dealers licence holders will need to notify the MHRA of their intention to continue importing QP-tested and batch released medicines from EU/EEA countries
1 year after exit day	• Deadline for providing MHRA with relevant baseline data for CAPs converted automatically into UK MAs
31 July 2021	• Deadline for Marketing Authorisation Holder to be established in the UK • Deadline for QPPV to be established in the UK • Deadline for parallel import licence holders to be established in the UK
2 years from exit day	• Deadline for wholesalers to name a Responsible Person for Import
31 December 2021	• MHRA deadline for amending administrative details on packaging and in package leaflets

TBC by EU27	• Deadline for all batch testing facilities to be fully transferred to the EU27/EEA for placing a medicine on the market in the EU

Q2: Will renewal applications due to be submitted to the EMA after EU Exit need to be resubmitted to MHRA by the same deadlines?

Yes. All MAs in the UK will become purely national on leaving the EU. Therefore, any submissions due to be submitted to EMA after exit day will also need to be submitted to MHRA by the same deadlines.

Any pending and new applications to renew an MA will therefore only be processed to conclusion after exit as national renewals and the relevant national procedures will be followed. All renewal dates for EU-licensed products will remain unchanged when converted into UK MAs and any new renewal applications should be submitted to the MHRA nine months before expiry, in line with current best practice.

For renewal applications submitted before exit day related to MAs granted under MRPs or DCPs, but where no decision has yet been made, the MHRA will conduct the assessment of the application, taking into account the stage that the application has reached on exit day. Where a final decision has already been made but has not been processed in the UK before exit day, the MHRA will implement the agreed outcome.

Further information on this is available here:

https://www.gov.uk/guidance/how-renewals-of-marketing-authorisations-will-be-handled-in-a-no-deal-scenario.

Q3: Will UK-based companies exporting medicinal products from the UK to the EU need to secure a licence through the EMA?

Once the UK leaves the EU, companies exporting human medicines from the UK to the EU will need to ensure that they have the correct Marketing Authorisations in place for the markets they are intending to sell in – ie a relevant CAP, MRP or DCP authorisation.

On the recognition of QP certification in the EU, the most recent guidance from the European Commission notes that competent authorities may allow Marketing Authorisation Holders, **for a limited period of time**, to rely on quality control testing performed in the UK under the following conditions:

1. A batch release site in the EU27 is identified by the Marketing Authorisation Holder by the withdrawal date
2. The batch release site is supervised by a qualified person established in the EU27 by the withdrawal date

3. The establishment designated by the third party conducting the quality control testing may be verified by a competent authority of the EU27, including on the spot checks
4. All necessary steps have been taken to prepare the transfer of the quality control testing site from the United Kingdom to the EU27

In order to make use of this exemption, affected Marketing Authorisation Holders must immediately notify the relevant national competent authority that granted the MA (or EMA in the case of CAPs) without delay. In the notification, the MAH must:

- Specify the batch release site in the EU27
- Confirm that the QP established in the EU27 is responsible for the quality control testing site in the UK
- Confirm and set out the precise timetable for transfer of quality control testing site to the EU27
- Specify the period of time and batches that are requested to be exempted, strictly restricted to what is necessary
- Commit to providing batch testing results for those batches from the existing facilities within the UK
- Transfer samples of those tested batches, together with the testing results, to the batch release sites in the EU27 in time to make them available for inspection

All batch testing facilities must be fully transferred to the EU27/EEA and the necessary regulatory submissions are completed. The deadline for this when EU Exit day was 31 October 2019 was 1 January 2020; however, a revised deadline is expected from the EU following the extension of EU Exit to 31 January 2020.

Further information on this is available here:
https://ec.europa.eu/health/sites/health/files/files/documents/brexit_batchtesting_medicinalproducts_en.pdf

https://www.hma.eu/535.html

Q4: Can the UK be a Reference Member State for MRP authorisations?

No. From exit day, the MHRA will no longer be part of the European regulatory network and so will no longer be able to be an RMS for MRP or DCP authorisations in the EU. This is regardless of whether a deal is secured or not. Companies will therefore need to have a new RMS in place for exit day for MRP or DCP authorised products if they haven't already switched from a UK RMS to an EU RMS.

Further information on this is available here:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/BREXIT/CMDh_361_2017_Rev3_01_2019_clean_-_QA_on_BREXIT.pdf

Q5: Can the Government legally ban exports of medicines that are in short supply?

The Human Medicines Regulations 2012 allow the Government to place a ban on the parallel export of medicines that are in short supply in the UK. The Government published a list of medicines that cannot be parallel exported from the UK on 3 October 2019. This list can be found here and is updated on a regular basis. Parallel export of a medicine on the list is considered a breach of regulation 43(2) of the Human Medicines Regulations 2012 and a contravention of the wholesale dealer licence. It may lead to regulatory action by the MHRA, which could include immediate suspension of the wholesale dealer licence.

Further information on this is available here: https://www.gov.uk/guidance/parallel-export-and-hoarding-of-restricted-medicines

Q6: Will the Government be sharing advice on any changes to regulation in the event that a deal is secured with the EU?

As a deal has not yet been passed by the UK and EU parliaments, there is currently no guidance on any changes that might result from such a deal with the EU. The deal agreed in principle with the EU in October 2019 is therefore not guaranteed to pass in its current form. As such, the Government has not published any guidance for companies to prepare for a deal, with advice focusing on supporting preparations for a no deal exit.

Changes to the regulation of medical devices

Q7: What are the key dates and deadlines to be aware of?

The EU and UK Government have agreed to extend the deadline for the UK leaving the EU from 31 October 2019 to 31 January 2020, with an earlier exit permitted if relevant legislative agreements are completed before this time.

Table 2 sets out the relevant deadlines as they are stated within current government guidance, correct as of 29 October 2019.

Table 2

Day 1 of EU Exit	• A new medical devices regulatory system will be in place in the UK
May 2020	• Implementation of the new EU Medical Devices Regulations in the UK
4 months after exit day	• Deadline for registering Class III, Class IIb implantable, Active implantable, and IVD List A medical devices with the MHRA • Deadline for registering the UK Responsible Person for the above products*
8 months after exit day	• Deadline for registering Class IIb non-implantable, Class IIa, IVD List B, and Self-test IVD medical devices with the MHRA • Deadline for registering the UK Responsible Person for the above products*
12 months after exit day	• Deadline for registering Class I, Self-certified IVDs, Class A IVDs medical devices with the MHRA • Deadline for registering the UK Responsible Person for the above products*

**Where a device manufacturer is not established in the UK, registration of a product with the MHRA must be undertaken by a 'UK Responsible Person' established in the UK and with a UK registered address who will take responsibility for the product in the UK.*

Timelines for **CE Marking and Notified Bodies** are as follows:

- Certificates that have already been issued by UK-based Notified Bodies prior to EU-Exit day, will continue to be valid for the UK market after EU-Exit day. These UK-based Notified Bodies will continue to oversee these devices and their manufacturers, to ensure continued compliance with the applicable standards of safety and performance. The MHRA will continue to oversee the activities of UK-based Notified Bodies.
- **From EU Exit day:**
    - If you wish to export your medical device to the EU, you will need a Notified Body based in an EU Member State.
    - If you wish to place a new device, which requires a Notified Body to carry out a conformity assessment, on to the UK or EU market, you will need to use a Notified Body based in an EU Member State. Once the conformity assessment has been successfully

completed, you can place a CE mark on your device and place the product on the UK or EU market.

Further information can be found here: https://www.gov.uk/government/publications/medical-devices-uk-notified-bodies https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main

Q8: Will the EU REACH Regulation still stand following a no-deal EU Exit?

In the event that the UK leaves the EU without a deal, the EU REACH Regulation will be brought into UK law by the European Union (Withdrawal) Act 2018.

Further information on this is available here: https://www.hse.gov.uk/brexit/reach.htm

Q9: What is the limit to the number of devices that can be registered with the MHRA?

The guidance does not reference a limit to the number of devices that can be registered. It states that you will be charged a statutory fee of £100 per new registration application. Groups of similar products can come under a single registration, since the MHRA requires most products to be registered at the level of Global Medical Device Nomenclature (GMDN) code. However, this will change when the new EU Medical Devices Regulations are introduced in the UK in May 2020 when all products will need to be registered individually.

Further information on this is available here:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario

Q10: How will medical device labelling look following a no-deal EU Exit?

The UK regulatory system put in place on day 1 of EU Exit will mirror all key elements contained in the EU Medical Devices Legislation, including that relevant labelling requirements will continue to apply such as the requirement for products to carry a CE mark. Devices that require conformity assessment must also include the Notified Body number in their labelling. Therefore, changes in the Notified Body conducting conformity assessments will require changes to Notified Body numbers appearing on the device and packaging.

The UK will continue to accept labelling in the English language, which includes information from other jurisdictions (eg Ireland), on the condition that information complies with all UK requirements.

Planned changes to labelling in line with the Medical Devices Directive requirements will go ahead in May 2020.

Further information on this is available here:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario

Q11: Will the new UK Responsible Person role include liability?

As the UK Medical Devices Regulations 2002 (as amended by the UK MDR 2019) are safety regulations for the purposes of the Consumer Protection Act, it is possible that a UK Responsible Person may be proceeded against under the Regulations or under the Consumer Protection Act 1987 if they fail to perform any of their obligations. It is also possible that an individual could be held liable. Whilst not a requirement until Part VIII of the UK MDR 2019 fully applies in May 2020, the manufacturer may already have insurance in place. The UK Responsible Person may wish to include in its mandate whether it has the benefit of that insurance, or an indemnity based on the existence of that insurance, from the manufacturer.

Further information on this is available here:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario#uk-responsible-person

Q12: Can the UK Responsible Person be an importer?

Yes. If you are a UK-based importer and you wish to place a device on the market, you must have the authority from the manufacturer before doing so. This means that you will become a UK Responsible Person. If you have no-one available to become a UK Responsible Person, you may wish to speak to existing EU Authorised Representatives in the UK to determine whether they will be offering services as a UK Responsible Person on your behalf as the importer.

Further information on this is available here:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario#uk-responsible-person

Q13: If a manufacturer already has arrangements in place for a UK Responsible Person for their products, do we, as a distributor of these products, also need to have a UK Responsible Person in order to sell them in the UK?

If the manufacturer is responsible for placing the product on the UK market and has a UK Responsible Person in place for their products and you are just the distributor and not involved in placing the product on the UK market, you do not need a UK Responsible Person.

Further information on this is available here:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario#uk-responsible-person

http://www.legislation.gov.uk/ukdsi/2019/9780111179260/pdfs/ukdsi_9780111179260_en.pdf#page=41

Q14: Will there be labelling changes to reflect the role of the Responsible Person?

There will be no labelling changes required to reflect the role of UK Responsible Person. Planned changes to labelling in line with the Medical Devices Directive requirements will go ahead in May 2020.

Further information on this is available here:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario#uk-responsible-person

Changes to nutrition legislation with regard to food supplements

Q14: What are the key dates and deadlines to be aware of?

The EU and UK Government have agreed to extend the deadline for the UK leaving the EU from 31 October 2019 to 31 January 2020, with an earlier exit permitted if relevant legislative agreements are completed before this time.

Table 3 sets out the relevant deadlines as they are stated within current government guidance, correct as of 29 October 2019.

Table 3

Day 1 of EU Exit	• Any food, including food supplements, that has not cleared customs by this time will not be permitted to "sell through" • New UK Nutrition and Health Claims Register applies
21 months after exit day	• End of transition period to ensure relevant labelling changes are made to food supplement products

Q15: Will food supplement products imported from or exported to the EU need to have health certificates?

Imports from non-EU countries:

For products of animal origin (POAO) subject to veterinary checks imported from non-EU countries, health certificates and other documentation currently used for imports will be accepted by the UK for six months after the UK leaves the EU. After this time, companies will need to use a new UK health certificate.

Imports from EU countries:

Imports from the EU will not need to be accompanied by a health certificate, unless a health certificate was required on the commodity before the UK left the EU. Further information on requirements for importing animals and POAO is available here:

https://www.gov.uk/guidance/importing-animals-animal-products-and-high-risk-food-and-feed-not-of-animal-origin-if-the-UK-leaves-the-EU-with-no-deal

Exports to EU countries:

To export animals, POAO or germplasm from the UK to the EU, companies will need an export health certificate, which will need to be paid for in advance. Further information on requirements for exporting animals and POAO is available here:

https://www.gov.uk/guidance/exporting-animals-animal-products-fish-and-fishery-products-if-the-uk-leaves-the-eu-with-no-deal

Changes to customs authorisations

Q16: Will each additional product imported from the EU to the UK need to be registered with the HMRC as an amendment to current authorisation at the point at which it is imported? Or can they be registered through periodic submissions?

The Government has not advised that periodic submissions will be allowed. Companies should write to their HMRC authorisation team to request an amendment to their authorisation for customs special procedures if there are any changes to:

- The range of commodity codes
- Quantities
- Values
- Any other details specified in your current authorisation

Further information on this is available here:

https://www.gov.uk/guidance/changes-to-your-customs-authorisations-if-the-uk-leaves-the-eu-without-a-deal