October 2019

EU Exit Business Readiness: preparing for a no deal
Government advice of relevance to the consumer healthcare industry

Introduction

This document provides an overview of government advice of relevance to the consumer healthcare industry in preparation for leaving the EU without a deal on 31 October. It covers guidance related to the regulation of medicines, medical devices and food supplements, as well as selected wider business readiness steps, such as the changes to customs procedures, intellectual property and use of personal data.

Of particular importance to the consumer healthcare industry are the following points:

- If the UK leaves the EU without a deal, the UK's involvement in the European regulatory network will end and the MHRA will take on the EU's current regulatory functions for medicines and devices in the UK.

- To place a medicine on the EU market, the Marketing Authorisation Holders (MAHs) and applicants must be established in the EU/EEA. The Qualified Person for Pharmacovigilance (QPPV) and the Pharmacovigilance System Master File (PSMF) must be based in the EU/EEA.

- To place a medicine on the UK market, the MAH and QPPV can initially be UK or EU/EEA based, but the MAH and QPPV must be established in the UK by the end of 2020. All Centrally Authorised Products (CAPs) will be converted into UK Market Authorisations (MAs) on 31 October 2019. Any new products in the UK will need to go through a national assessment by the MHRA.

- To make sure there is continuity of supply of medicines, the UK will continue to accept batch testing of human medicines carried out in countries named on a list set out by the MHRA (including EU/EEA countries and those third countries with which the EU currently has a mutual recognition agreement in place).

- The UK will continue to recognise Qualified Person (QP) certification from the EU/EEA after the UK leaves the EU, for both medicines manufactured in the EU/EEA and those manufactured in a third country but imported into the UK from the EU/EEA.

- For medical devices, conformity assessment carried out by UK notified bodies (NBs), designated by a UK Competent Authority, will not be recognised by the EU. Any European presence of a UK NB, designated by a European Competent Authority, will be in compliance with EU law and certificates will therefore be valid in the EU.

- For a time-limited period, the UK Government will continue to allow devices to be placed on the UK market that are in conformity with the applicable EU Directive. Relevant

labelling requirements will continue to apply including the requirement for products to carry a CE mark.

- To support the continued supply of medical devices to the UK market, the UK Government will give UK-based NBs an ongoing legal status and continue to recognise the validity of certificates that they issued prior to exit day. Under UK legislation a new role, known as a UK Responsible Person, will be created for manufacturers based outside of the UK.

Further details are outlined below, alongside links to the original national guidance, in the following categories:

- Regulation of medicines,
- Regulation of medical devices,
- Changes to nutrition legislation
- Changes to customs authorisations
- Intellectual property
- Horizon 2020 funding
- Employing EU citizens
- Personal data
- Structuring cross-border business operations
- Public-sector procurement

In addition to this document, PAGB will be hosting two member webinars on **10 October** and **14 October**. These webinars will enable members to be taken through the relevant elements of the guidance, discuss examples of best practice from industry colleagues and ask any questions. Please contact donna.castle@pagb.co.uk for further details on these webinars.

All guidance and hyperlinks are current as of 27 September 2019. A full bibliography of guidance referenced throughout this document is found in the Appendix.

Full government guidance is available here and if you have any technical questions the Business Support Helpline can be contacted at: enquiries@businesssupporthelpline.org.

Regulation of medicines[1,2]

As most consumer healthcare medicines hold national licenses, the most important changes to take note of within this section include: legal presence requirements; batch testing and certification; and the Government's contingency plans for rerouting supplies. Of particular note is the need for MAH, QP and QPPV to have an established presence both in the UK and in the EU/EEA to be able to place medicines on both the UK and EU markets.

Actions for companies supplying medicines to the UK from or through the EU:

- Secure capacity for rerouting freight away from Dover, Barking and Folkestone in the UK and Dunkirk, Calais, or Boulogne-sur-Mer Coquelles in France after 31 October 2019 to avoid disruption
- Stockpile a minimum of 6 weeks' additional supply in the UK by 31 October (for POM/P medicines)
- Prepare logistics and supply chains to meet the new customs and border requirements for both important and exporting (see changes to customs authorisations below)
- Ensure continued supply to the NHS as part of the contingency programme
- Make alternative air freight plans for products with a short shelf-life or where production constraints mean stockpiling is not possible (guidance on air freight can be found here)
- Notify the Department of Health and Social Care (DHSC) of your company's plans

1. Regulatory changes overview

1.1. The UK's participation in the European Medicines Regulation Network (EMRN) will end if the UK leaves the EU without a deal on 31 October and the MHRA would take on the functions currently undertaken by the EU for human medicines on the UK market.

1.2. All currently granted Central Authorised Products (CAPs) will automatically become UK MAs on exit day, although there will be a short period of time after exit day within which holders can opt out of having UK MA. MAHs undergoing CAP conversion and variations will have one year from exit day to provide MHRA with relevant baseline data. Full details on what documentation will need to be submitted by the MAH within a year of exit day can be found here. Any converted EU MA will have the same renewal date in the UK as in the EU.[3]

[1] Department of Health and Social Care, *Businesses supplying medicines and medical devices: preparing for Brexit*, 17 September 2019, available at: https://www.gov.uk/guidance/businesses-supplying-medicines-and-medical-devices-what-to-expect-on-day-one-of-a-no-deal-scenario

[2] Medicines & Healthcare products Regulatory Agency, *Further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal*, 3 September 2019, available at: https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal

[3] Medicines & Healthcare products Regulatory Agency, *Converting Centrally Authorised Products (CAPs) to UK Marketing Authorisations (MAs) in a no-deal Brexit, 'grandfathering' and managing lifecycle changes*, 18 March 2019, available at: https://www.gov.uk/guidance/converting-centrally-authorised-products-caps-to-uk-marketing-authorisations-mas-in-a-no-deal-scenario-grandfathering-and-managing-lifecycle-ch

1.3. All medicinal products approved in the UK on or before the day the UK leaves the EU via a decentralised (DCP) or mutual recognition (MRP) procedure have been issued with a national (UK) MA. These MAs will be unaffected and remain valid in the UK. Any subsequent variation to the MA should be submitted as a national variation using current procedures (see details below on variations).[4]

1.4. For MRPs where the UK is the Reference Member State (RMS), a national (UK) MA has already been granted in the UK before the start of the MRP. For an MRP where the UK is a concerned Member State (CMS), a national (UK) MA is issued if a positive outcome is reached.

1.5. UK abridged licences which reference an EU reference product which have been granted (or subject to pending applications) prior to exit day will remain valid after exit day. Any new abridge applications will need to be based on reference product authorised in the UK, which include CAPs which have been converted to UK MAs or non-converted CAPs which were granted prior to exit day.

1.6. For renewal applications submitted before exit day which relate to MAs granted under MRPs or DCPs but where no decision was made before exit day, the MHRA will conduct the assessment of the application. The assessment will take into account the point in the overall procedure that the application has reached on exit day. Where a final decision has already been taken by the lead authority but has not been processed in the UK before exit day, the MHRA will take the necessary steps to implement the agreed outcome of the procedure.[5]

1.7. Any new renewal applications post-exit day should be submitted to MHRA in line with current best practice and in the same time frame (9 months) before expiry

1.8. The MHRA will have oversight of all pharmacovigilance activities: risk management plans, reports of suspected adverse drug reactions from the pharmaceutical industry, periodic safety update reports (PSURs) and post-authorisation safety studies (PASS) will need to be submitted to and assessed by the MHRA from exit day.[6] The Good Vigilance Practices (GVP) modules will remain in force, but may in time be replaced with UK guidance on good pharmacovigilance practice.

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[4] Medicines & Healthcare products Regulatory Agency, *Guidance on handling of Decentralised and Mutual Recognition Procedures in a no-deal Brexit*, 8 August 2019, available at: https://www.gov.uk/guidance/guidance-on-handling-of-decentralised-and-mutual-recognition-procedures-in-a-no-deal-scenario

[5] Medicines & Healthcare products Regulatory Agency, *How renewals of Marketing Authorisations will be handled in a no-deal Brexit*, 18 March 2019, available at: https://www.gov.uk/guidance/how-renewals-of-marketing-authorisations-will-be-handled-in-a-no-deal-scenario

[6] Medicines & Healthcare products Regulatory Agency, *Further guidance on pharmacovigilance procedures in the event the UK leaves the EU without a deal,* 18 March 2019, available at: https://www.gov.uk/government/publications/guidance-on-pharmacovigilance-procedures-in-the-event-the-uk-leaves-the-eu-without-a-deal/further-guidance-on-pharmacovigilance-procedures-in-the-event-the-uk-leaves-the-eu-without-a-deal

2. MA assessment routes

2.1. The MHRA would offer three new assessment procedures for applications for products containing new active substances and biosimilars (alongside the existing 210-day national licensing route):

2.1.1. A targeted assessment for products submitted to the EMA and in receipt of a CHMP positive opinion, completed within 67 days of submission. It is available for products containing new active substances or biosimilar molecules.
2.1.2. A full accelerated assessment, with a timeline of no more than 150 days, is available for all products containing new active substances.
2.1.3. A 'rolling review', which allows companies to make an application in stages throughout the product development to better manage development risk. The rolling review provides on-going regulatory input and feedback to enhance the development of novel medicines.

2.2. MHRA will work with industry to review the current national licensing route from 210-days to 180 days.

2.3. For CAPs that are still pending on exit day, and without a positive opinion from the CHMP, the handling will be determined by the stage of the procedure on the application:[7]

2.3.1. If the procedure has reached day 181 of the assessment timetable, the MHRA will complete the assessment tailored to the outstanding issues to reach an assessment decision as soon as practicable.
2.3.2. If the procedure has reached day 120 of the assessment timetable, there are two routes to completion: in-flight assessment, where the applicant submits the same application to the MHRA as has been submitted to the EMA (including the list of questions raised by the CHMP) to allow the MHRA to complete its assessment of the application at the same time as the EMA centralised procedure is ongoing; or the targeted assessment route, as outlined above.
2.3.3. If the procedure is still in the first phase of assessment, it will need an independent assessment by the MHRA after a submission has been made through one of the three routes set out above.

3. Variations[8]

3.1. Any pending variations for Marketing Authorisations in European Procedures will automatically become national variations after EU Exit day. They will be processed to their conclusion under the relevant national procedure. The procedures detailed under Chapter IIa of the Human Medicines Regulations 2012 (HMRs), which

[7] Medicines & Healthcare products Regulatory Agency, *Guidance on the handling of applications for Centrally Authorised Products (CAPs) pending on exit day*, 18 March 2019, available at: https://www.gov.uk/guidance/guidance-on-the-handling-of-applications-for-centrally-authorised-products-caps-pending-on-exit-day

[8] Medicines & Healthcare products Regulatory Agency, *Guidance on how variations to Marketing Authorisations (MAs) will be handled after exit day if there is no-deal*, 18 March 2019, available at: https://www.gov.uk/guidance/guidance-on-how-variations-to-marketing-authorisations-mas-will-be-handled-after-exit-day-if-the-is-no-deal

specifically applied to variations to purely national MAs, will continue to apply to both pending and new variations to UK MAs, all of which will be purely national after exit day and can be found in new regulation 65C and Schedule 10A to the HMRs.

3.2. In addition, unless specifically highlighted under section 3, the current variations classification guidelines, which explains the type of variation (Type IA, Type IAIN, Type IB, Type II or Extension) to submit and, where relevant, the conditions to be met and any required supporting documentation, will continue to apply.

3.3. Any extension application should be submitted in accordance with the procedures for new Marketing Authorisations. The variations classification guidelines will continue to apply until the MHRA issues any revised guidance in the future.

3.4. The UK will recognise any Article 5 recommendation published by the CMDh before exit day. Any specific request from an MAH concerning the classification of a variation, which is still pending on exit date or is submitted after exit day will need to be submitted directly to the MHRA, who will issue its own recommendation.

4. Fees

4.1. The relevant MHRA fee changes that will be introduced are:

4.1.1. fees for new targeted assessment procedures, specifically £62,421 for a major application for an MA for a new active substance, and £17,330 for a complex abridged application for an MA for a biosimilar
4.1.2. fees of £8,309 for assessment of a PASS protocol, and £8,309 for assessment of results of a PASS study
4.1.3. a fee of £51,286 to undertake a Pharmacovigilance Major Safety Review
4.1.4. a fee of £890 for a single assessment of PSURs
4.1.5. changes to Renewals fees so that all new active substances (including CAPs that are converted to UK MAs) are subject to a single renewal fee of £9,682 for the five-year renewal application from when the licence was first granted (either in the UK or EU for a CAP 'grandfathered' into the UK)

5. Legal presence requirements[9][10]

5.1. A MAH should be established in the UK by 31 July 2021. Where the MAH is not established in the UK on exit day, companies will be expected to put in place a UK-based contact person within 4 weeks of leaving the EU who will be accessible to the licensing authority in respect of any matter relating to the MA.

[9] Medicines & Healthcare products Regulatory Agency, *Further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal*, 3 September 2019, available at: https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal

[10] Medicines & Healthcare products Regulatory Agency, *Guidance on qualified person responsible for pharmacovigilance system master files (PSMF) in a no-deal Brexit*, 7 August 2019, available at: https://www.gov.uk/guidance/guidance-on-qualified-person-responsible-for-pharmacovigilance-qppv-including-pharmacovigilance-system-master-files-psmf-if-the-uk-leaves-the-eu-w

5.2. A Qualified Person for Pharmacovigilance (QPPV) should be established in the UK on day one. A temporary exemption until 31 July 2021 will allow the EU QPPV to assume responsibility for UK MAs until a QPPV who resides and operates in the UK can be established.

5.3. A Qualified Person (QP) for products manufactured in the UK or directly imported into the UK from a country not in the EU or EEA must reside and operate in the UK (see batch testing section below).

5.4. The UK MAH also has the legal obligation to maintain and make available upon request a pharmacovigilance system master file (PSMF) that describes the pharmacovigilance system for UK authorised products (UK PSMF). The UK PSMF must be located in, or accessible electronically from, the UK at the same site at which adverse reaction reports may be accessed. Specific details on all requirements are found here.

5.5. The MHRA will retain the ability to require independent re-testing of medicines and the ability to require withdrawal of a product from the market as now.

5.6. In the event of a change in license or transfer to UK MAH and QPPV, full details of what documents will need to be submitted to the MHRA and when by can be found here.

6. Batch testing and certification

6.1. After leaving the EU without a deal, the UK will no longer be a member of the European Medicines Agency (EMA). However, the UK Government will continue to recognise batch testing of human medicines carried out in either a) the EU or EEA countries or b) third countries with which the EU has a Mutual Recognition Agreement. They will also continue to recognise QP Certification from EU/EEA countries after EU Exit.

6.2. A QP based in a country approved for import (EU and EEA countries) will still be able to certify, release and assure compliance with the MA and GMP for medicines that are either a) manufactured in a country on the MHRA's approved country for import list (EU and EEA countries) or b) manufactured in a third country but imported into the UK from a country on the MHRA's approved country for import list.

6.3. To continue this activity, wholesale dealers licence holders will need to notify MHRA within 6 months of EU Exit of their intention to continue this. A revised Wholesale Dealers Authorisation (WDA) will be issued including importation of medicines from countries on a list.

6.4. Holders of this amended authorisation will be required to put in place an assurance system to ensure any medicines they import have been QP certified. This will not

require any QP re-certification. The assurance system will be overseen by a new role of Responsible Person for Import (RP-I).[11]

6.5. The RPi may delegate the activities but remains responsible. They must implement a system for confirming the QP certification has taken place when importing to the UK products from a listed country (initially this will be countries in the EEA):

6.5.1. A UK licensed medicine for use in the UK
6.5.2. A UK licensed medicine as an introduced medicine for supply to another third country
6.5.3. An EEA licensed medicine - supply to fulfil special clinical needs
6.5.4. An EEA licensed medicine imported as an introduced medicine for supply to another third country
6.5.5. An EEA licensed medicine for use as starting material for a parallel import

Full requirements to be a RPi and application details are here. Wholesalers will have 2 years post EU Exit to name a RPi on their authorisation, but will be expected to verify the above points from the day after EU Exit.

6.6. These arrangements will continue until the Government thinks any further change is necessary. Any changes will be consulted on with industry beforehand and at least two years' notice will be given to allow industry to prepare.

6.7. A Manufacturer's Licence for Import (MIA) will continue to be required for all other forms of import of human medicines being supplied onto the UK market.

7. Packaging and leaflets

7.1. The MHRA will give industry until the end of 2021 to amend certain administrative details on the packaging and in package leaflets for products already on the market, including:

7.1.1. UK administrative information such as the UK MAH's name and address
7.1.2. UK product licence number
7.1.3. Up-to-date information on the manufacturing site

7.2. The MHRA will continue to accept proposals for packaging and leaflets in the English language that include information from other jurisdictions (eg Ireland), on condition that this information complies with UK requirements and the information in all languages conveys the same message

7.3. The UK is proceeding with the implementation of the EU requirements for new safety features to prevent the entry into the legal supply chain of falsified medicinal products in the UK. However, on leaving the EU without a deal, it is expected that UK stakeholders would no longer be able to comply with the requirement to verify

[11] Medicines & Healthcare products Regulatory Agency, *Acting as a Responsible Person (import) after Brexit*, 4 October 2019, available at: https://www.gov.uk/government/publications/importing-medicines-from-an-eea-state-which-is-on-an-approved-country-for-import-list/guidance-for-the-role-of-the-responsible-person-import

and authenticate, and as such legal obligations to do so would be removed for all actors in the UK supply chain.

7.4. Packs containing the Falsified Medicines Directive (FMD) safety features would still be accepted in the UK, provided they are in line with other UK packaging requirements. The options for a future UK falsified medicines regulatory framework will be considered.

8. Parallel imports

8.1. Medicinal products that hold a MA in another Member State, or are CAPs, will still be able to be imported under a parallel import licence subject to MHRA obtaining the necessary information to show they are essentially similar to a product that has been granted a UK MA.

8.2. The parallel import regime will remain limited to EU and EEA countries and the MHRA will be able to vary, suspend or revoke a parallel import licence if the UK reference product is varied, suspended or revoked.

8.3. Parallel import licence holders will in future need to be established in the UK – those holding licences elsewhere in the EU or EEA will have until 31 July 2021 to effect this change. Until they have done so, companies will be expected to put in place a UK-based contact person within 4 weeks of leaving the EU, who is accessible to the licensing authority in respect of any matter relating to the parallel import licence.

9. Re-routing supplies[12]

9.1. DHSC is procuring an express freight services able to deliver small batches within 24 hours and a 2 to 4-day pallet delivery service.

9.2. The Department for Transport (DfT) is procuring roll-on, roll-off freight capacity on which medicines and medical products would be prioritised (including GSL).

10. Manufacturer's Authorisation licenses[13]

10.1. To qualify for a manufacturer license to make, assemble or import human medicines to the UK, you must show the MHRA that you comply with EU GMP and pass regular inspections at your site.

10.2. To qualify for a wholesaler license to sell or supply medicines to anyone other than the patient using the medicine, you must comply with good distribution practice and pass regular inspections or your site.

[12] Department of Health and Social Care, *Businesses supplying medicines and medical devices: preparing for Brexit*, 17 September 2019, available at: https://www.gov.uk/guidance/businesses-supplying-medicines-and-medical-devices-what-to-expect-on-day-one-of-a-no-deal-scenario

[13] Department of Health and Social Care, *Businesses supplying medicines and medical devices: preparing for Brexit*, 17 September 2019, available at: https://www.gov.uk/guidance/businesses-supplying-medicines-and-medical-devices-what-to-expect-on-day-one-of-a-no-deal-scenario

11. Reporting supply issues[14]

11.1. If you experience disruption to your supplies or feel there is the potential for disruption which usual procedures can't resolve, you can report it to the **National Supply Disruption Response (NSDR)**. Contact details for the NSDR will be shared with suppliers before the UK leaves the EU.

11.2. The Government has banned the export of certain products that have been identified as required to meet the needs of UK patients, are currently being parallel exported / at threat of being parallel exported; and is either contributing to or may contribute to a shortage of that medicine in the UK. The UK Government has legal powers to do this as set out in the Human Medicines Regulations 2012. The full list of banned products can be found here.

[14] Department of Health and Social Care, *Businesses supplying medicines and medical devices: preparing for Brexit*, 17 September 2019, available at: https://www.gov.uk/guidance/businesses-supplying-medicines-and-medical-devices-what-to-expect-on-day-one-of-a-no-deal-scenario

Regulation of medical devices[15,16]

Of particular relevance to the consumer healthcare industry will be the new regulatory system that the MHRA implements for medical devices. Whilst based on the latest EU Medical Devices Regulations (still set to be implemented in the UK in 2020 regardless of whether the UK secures a deal or not), there will be new requirements including the establishment of a UK Responsible Person. In addition, all medical devices will need to be registered with the MHRA.

Actions for companies supplying medical devices to the UK from or through the EU

- Review supply chains, assess how leaving the EU without a deal would impact product ranges and then make contingency plans
- Read DHSC's letter to suppliers of medical devices

12. Regulatory changes

12.1. The UK's current participation in the European regulatory network for medical devices would end, and the MHRA would take on the responsibilities for the UK market currently undertaken through the EU system.

12.2. The EU Directives on in vitro diagnostics medical devices (IVDD), active implantable medical devices (AIMDD) and medical devices will continue to apply to the UK through the UK Medical Devices Regulations 2002.

12.3. The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 (UK MDR 2019) will amend the Medical Devices Regulations 2002, and the UK will have a regulatory system in place on 1 November 2019, which will mirror all the key elements contained in the MDR. This will be brought into force in line with the transitional timetable being followed by the EU for the full application of the Regulations (2020 for MDR).

13. The role of the MHRA

13.1. The MHRA will continue to perform market surveillance of medical devices on the UK market and be able to take a decision over the marketing and supplying of a device in the UK, regardless of the position of the European regulatory network, or any post-exit decision of the European Court of Justice.

[15] Medicines & Healthcare products Regulatory Agency, *Further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal*, 3 September 2019, available at: https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal

[16] Medicines & Healthcare products Regulatory Agency, *Regulating medical devices in the event of a no-deal Brexit*, 18 September 2019, available at: https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario

14. Role of those manufacturing and supplying devices

14.1. Based on the European Commission's Notice to Stakeholders of 22 January 2018, it is generally understood that UK-based Authorised Representatives will no longer be recognised in the EU. Under UK legislation a new role, known as a UK Responsible Person, will be created for manufacturers based outside of the UK (details on this new role are set out below).

14.2. The UK MDR 2002 sets out requirements that a manufacturer must meet. Manufacturers seeking conformity with the EU Directives transposed by that statutory instrument should continue to follow these criteria. A new Schedule (2A) has been inserted into the UK MDR 2002 which sets out how the Annexes to the Directives which are cross referenced in Parts II, III and IV of the UK MDR 2002 should be read in a UK specific context after the UK has left the EU.

14.3. There are additional responsibilities for manufacturers wishing to comply with Part VIII or Part IX of the UK MDR 2002 (as amended by the UK MDR 2019), which transposes the relevant requirements from the EU MDR. These additional responsibilities include, but are not limited to:

14.3.1. Correctly classifying the device against the new risk classification criteria
14.3.2. Meeting general safety and performance requirements, including for labelling and technical documentation and quality management systems
14.3.3. Meeting increased requirements for clinical evidence
14.3.4. Having a person responsible for regulatory compliance in place
14.3.5. Meeting the new vigilance reporting timescales and creating an annual periodic safety update report

15. UK Responsible Person

15.1. A new role – the UK Responsible Person – has been created under the UK MDR 2002 (as amended by the UK MDR 2019), applicable in a no-deal scenario. The UK MDR 2019 defines the UK Responsible Person as *"a person established in the United Kingdom who acts on behalf of a manufacturer established outside the United Kingdom in relation to specified tasks with regard to the manufacturer's obligations under these regulations"*.[17]

15.2. The UK Responsible Person must be established in the UK and acts on behalf of a manufacturer established outside the UK, to carry out specified tasks in relation to the manufacturer's obligations. This includes registering with the MHRA before the device is placed on the UK market.

15.3. Only a manufacturer or a designated UK Responsible Person can legally place a device on the UK market. This means that a single manufacturer may have several designated UK Responsible Persons. If you are a designated UK Responsible Person of a non-UK manufacturer, documentary evidence is required. This evidence should be in the form of a headed letter (letter of designation) or signed contract,

[17] The term "person" refers to either an individual (i.e. a sole trader) or a legal person (i.e. a company)

which states the company name and address for both the overseas manufacturer and the UK Responsible Person.

15.4. No labelling changes will be required to reflect the role of this UK Responsible Person.

15.5. The requirement for a manufacturer to have in place a UK Responsible Person is in line with the grace period for registering devices with the MHRA set out in Table 1 below. You must ensure that you have a designated UK Responsible Person by the time you register with the MHRA.

Table 1

4 months	Class III medical devices, Class IIb implantable medical devices, Active implantable medical devices, IVD List A
8 months	Class IIb non-implantable medical devices, Class IIa medical devices, IVD List B, Self-test IVDs
12 months	Class I medical devices, Self-certified IVDs, Class A IVDs

16. Authorised Representatives

16.1. In order to place devices on the EU market, manufacturers with an Authorised Representative based in the UK will need to establish a new Authorised Representative in an EU country.

17. Importers

17.1. If a person places a product on the market under Part VIII or Part IX of the UK MDR 2002 (as amended by the UK MDR 2019), a number of additional obligations will apply to importers, which will include, but are not limited to, verifying that:

17.1.1. The device has been CE marked;
17.1.2. The manufacturer is identified and has a UK Responsible Person, if required;
17.1.3. The device has been labelled correctly and a Unique Device Identifier (UDI) has been assigned to the device;
17.1.4. The device is registered with the MHRA.

18. Parallel importers

18.1. After the UK leaves the EU, parallel importing from the EU into the UK will not be possible. Any device that is imported from the EU and placed on the UK market will be treated as a new placing on the market, with all of the relevant manufacturer requirements applying to this importer, including the requirement to register the device with the MHRA. You will also need to ensure that there is a UK Responsible Person in place for this product.

19. Conformity of products

19.1. For a time-limited period, the UK Government will continue to allow devices to be placed on the UK market that are in conformity with the applicable EU Directive.

19.2. Relevant labelling requirements will continue to apply including the requirement for products to carry a CE mark and devices which currently require conformity assessment by a Notified Body (NB) must have a valid CE certificate.

19.3. UK-based NBs will no longer be recognised by the EU after the UK leaves without a deal, meaning the devices they have certified will no longer be in conformity with the applicable EU Directive. As such these products will not be able to be placed on the EU market.

19.4. UK-based NBs will be given an ongoing legal status and the validity of certificates that they issued prior to exit day will continue to be recognised in the UK. This means products covered by certificates issued by UK-based NBs will continue to be able to be placed on the UK market after exit day.

19.5. UK law will not require any changes to the labelling of affected products. Furthermore, the UK will continue to accept labelling in the English language, which includes information from other jurisdictions (such as Ireland), on condition that information complies with all UK requirements.

20. Market surveillance of devices

20.1. The MHRA would continue to perform market surveillance of medical devices on the UK market and be able to take a decision over the marketing of a device in the UK, regardless of the position of the European regulatory network, or any decision of the Court of Justice of the European Union (CJEU).

21. Registration of medical devices on the UK market

21.1. After exit day, all medical devices, AIMDDs, IVDs and custom-made devices will need to be registered with the MHRA prior to being placed on the UK market. There will be a grace period to allow time for compliance with the new registration process, which is the same as that for putting in place a UK Responsible Person as set out in Table 1 above.

21.2. The registration requirements will be as follows:

21.2.1. Initially the MHRA will require most products to be registered at the level of Global Medical Device Nomenclature (GMDN) code meaning that groups of similar products can come under a single registration. The exception is class III devices, which must have individual product information registered

21.2.2. Once the MDR fully applies, from May 2020, the UK will then mirror the new requirements within the legislation, which will mean individual registration of all products

Changes to nutrition legislation with regard to food supplements[18]

If the UK leaves the EU without a deal on 31 October, the EU Withdrawal Act 2018 will transpose EU Regulations and tertiary legislation relating to nutrition from exit day into UK law. The changes are minimal, with the only significant change to the regulatory framework being the transfer of responsibility for risk assessment and risk management processes from the EU to UK bodies.

22. Appropriate UK authorities

22.1. If the UK leaves the EU without a deal on 31 October, the EU Withdrawal Act 2018 will transpose EU Regulations and tertiary legislation relating to nutrition from exit day into UK law as the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Food and Feed Hygiene and Safety (Miscellaneous Amendments) (EU Exit) (No.2) Regulations 2019. This designates responsibility for risk assessment and risk management processes to UK bodies (UK Government and Devolved Administrations).

22.2. Whilst the appropriate authorities in the UK are devolved across the four nations of the UK, there are concurrent powers within the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 that allow the UK Secretary of State for Health and Social Care to make legislation for the whole UK, where Devolved Administrations agree.

23. Nutrition and health claims in the UK

23.1. A new UK Nutrition and Health Claims Register (UKNHC Register) will be adopted and all nutrition and health claims that are listed in the Community Register will be included. Current UK guidance for complying with this regulation, with the exception of any references to the EU, remains relevant under UK law.

23.2. Only nutrition and health claims listed in the UKNHC Register may be used in the UK after exit day. If the European Food Safety Authority (EFSA) or the European Commission has not taken a decision on any pending application related to a nutrition or health claim by exit day, an application must be submitted to the appropriate UK authorities for assessment for use in the UK. Evidence submitted should follow the guidelines provided by EFSA.

23.3. The UK Department of Health and Social Care and Public Health England have recruited an expert panel to sit on the UK Nutrition and Health Claims Committee (UKNHCC) who will undertake the evaluation of scientific evidence submitted in any dossier. Officials from the four home nations will provide risk assessment on any favourable opinion issued by the UKNHCC.

23.4. With regards to 'on hold' claims in the event the UK leaves the EU without a deal, the UK Government and Devolved Administrations will launch a call to evidence,

[18] Department of Health and Social Care, *Changes to nutrition legislation if there's a no-deal Brexit*, 30 September 2019, available at: https://www.gov.uk/government/publications/changes-to-nutrition-legislation-if-theres-no-eu-exit-deal?utm_source=4e4c5a5d-a8ff-4503-8d2a-22a0e8eb7451&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate

following which a policy decision would be made on the UK approach to 'on hold' claims and how they will be dealt with under the UK authorisation system. Existing 'on hold' claims may continue to be used in accordance with current regulations until a decision is made.

24. Vitamins, minerals and certain other substances

24.1. The list of substances which are prohibited, restricted or under scrutiny, under Annex III of Regulation 1925/2006 will be included in Section F of the Community Register of Vitamins, Minerals and Certain Other Substances. Any prohibitions or restrictions of use, or any substance under scrutiny placed into Annex III are applicable to ALL foods, including food supplements.

24.2. Amendments made at EU level since the publication of the Register on 26 March 2019 have not been reflected in the Register. At the time of writing (4 October 2019) this includes Regulation 2019/649, which restricts the level of trans fats, other than trans fats naturally occurring in fat of animal origin which may be present in any food.

25. Food supplements

25.1. Whilst food supplements are currently regulated by Regulations made in each devolved nation of the UK, they cross refer to the Annex of the Directive 2002/46/EC, which sets out the rules for vitamins and minerals used in food supplements.

25.2. Minor changes to this regulatory framework are being made by inserting the lists of vitamins and minerals used in the manufacture of food supplements contained in the EU Directive into the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 as Schedules. Current UK guidance for complying with this regulation, with exception to any references to the EU, remains relevant under UK law.

25.3. The UK Government has listed vitamins and minerals permitted for use in food supplements in the Schedules of the Nutrition (Amendment etc) (EU Exit) Regulations 2019.

25.4. Schedule 1 lists vitamins and minerals which may be used in the manufacture of food supplements; Schedule 2 lists the chemical forms of vitamin and mineral substance which may be used in the manufacture of food supplements.

26. Food Labelling

26.1. The UK Government has not implemented specific legislation in relation to food labelling and EU Exit. Guidance on preparing a food business for EU Exit can be found here. Guidance on general labelling issues can be found here.

26.2. The requirements for food labelling will remain broadly unchanged. However, the following areas, relevant to food supplements, will be subject to change:

26.2.1. For foods intended for the domestic UK market, the name and address of the food business operator (FBO) must be within the UK.
26.2.2. For foods intended for the EU market, the name and address of the FBO must be within the EU.

26.3. Both the UK Government and the EU have agreed that food labels may carry two addresses; one within the UK and one within the EU. The UK Government has also indicated that over stickering is acceptable. It is not yet clear if the European Union will accept over stickering.

26.4. The European Union has indicated that any food which has entered the EU before 23:00 UK time (00:00 Brussels time) on 31 October 2019 will be permitted to "sell through". Any food that has not yet cleared customs (i.e. is in transit) will not be permitted to "sell through".

26.5. The EU emblem will not be permitted for use on any food produced in the UK after exit day unless the EU has authorised its use. Nor will food produced in the UK be able to be labelled as being of EU origin.

26.6. Identification marks on products of animal origin will need to carry the letters "UK" within the oval mark. More information about this can be found here.

26.7. The UK Government has advised that there will be a 21-month transition period from exit day to ensure labelling changes can be made.

Changes to customs authorisations[19]

If the UK leaves the EU without a deal, a new customs procedure will be implemented, including new temporary tariffs on goods being imported into the UK. Whilst most goods of relevance to PAGB's members are expected to be tariff-free, you should check the temporary rates of customs duty on imports here. In addition, customs declarations will need to be made prior to crossing the UK border, up to 21 days earlier.

Actions to be ready to import from the EU to the UK after the UK leaves the EU

- Make sure your business has an Economic Operator Registration and Identification (EORI) number that starts with GB [Get an EORI number here]
- Decide who will make the import declarations (ie yourselves or a hired customs agent)
- Apply to make importing easier via transitional simplified procedures [register here] and set up a duty deferment account if you import regularly [apply here]
- Check the rate of tax and duty you'll need to pay – rates of customs on import after the UK leaves the EU are available here

You should first check whether current authorisations to use special and simplified procedures (known as customs facilitations) still apply. Your business must be established in the UK to use most customs facilitations (with the exception of temporary admission). Depending on the type of facilitation, and whether HMRC or another EU customs authority gave you that authorisation, you should check that you can carry on using it and whether it will be more limited.

27. Authorisation issued in the UK

27.1. If HMRC has authorised you to place goods into a customs special procedure in the UK, your authorisation will still be valid in the UK after EU exit and you'll also be able to use your authorisation to import goods from the EU along with any you already import from non-EU countries.

27.2. You should write to your HMRC authorisation team to ask for an amendment to your authorisation if there are changes to the range of commodity codes, quantities, values and any other details specified in your current authorisation.

28. Single authorisations issued in the UK for use in the EU

28.1. If HMRC has authorised you to place goods into a customs special procedure, including moving those goods into the EU, your authorisation will still be valid but in the UK only. This means that you can carry on importing goods into the UK under the authorised procedure after exit day.

28.2. You should write to your HMRC authorisation team to ask for an amendment to your authorisation if there are the same changes outlined in point 27.2.

[19] HM Revenue & Customs, *Changes to your customs authorisations in a no-deal Brexit*, 6 March 2019, available at: https://www.gov.uk/guidance/changes-to-your-customs-authorisations-if-the-uk-leaves-the-eu-without-a-deal

28.3. Current guidance issued by the EU is that authorisations for customs simplifications or procedures, such as customs warehousing, issued by the UK will no longer be valid in the EU after exit day.

29. Authorisations given by another EU customs authority

29.1. If you are named on an authorisation issued by another EU customs authority to place goods into a customs special procedure in the UK, you will not be able to receive goods in the UK under that authorisation after the UK leaves the EU.

29.2. Where you have had goods under an authorisation from another EU customs authority, you will have 12 months from the date the UK leaves the EU to discharge those goods from any customs special procedure.

30. Guarantees and special procedures

30.1. After the UK leaves the EU, in most cases you will not need a guarantee to cover your customs duty and import VAT. HMRC will give 12 months' notice before reintroducing guarantees.

31. Transit simplifications

31.1. You can carry on using HMRC-issued authorisations for transit simplifications, including authorised consignor and consignee status, after the UK leaves the EU.

32. Customs freight simplified procedures

32.1. If you are already authorised by HMRC to use customs freight simplified procedures, after the UK leaves the EU you will be able to use your authorisation to make simplified declarations for goods imported from the EU, as well as from non-EU countries.

33. Authorised economic operator

33.1. If you are established in the UK and you already hold authorised economic operator status issued by HMRC, your authorisation will be transferred automatically to the UK scheme after the UK leaves the EU. This will be a new UK status and will replace your existing EU status for your UK customs operations. You will be issued with a new certificate and logo which you should use in place of any existing certificate and logo.

33.2. Guidance issued by the EU is that economic operator status authorisations issued by the UK will no longer be valid in the EU after the UK leaves.

33.3. If you currently hold authorised economic operator status issued by another EU customs authority, which covers your customs operations in the UK, the UK will not recognise this, and it will not secure the benefits of the status in the UK after exit day

34. Temporary rates of customs duty (tariffs) on imports after a no-deal exit

34.1. If the UK leaves the EU without a deal, you may need to pay different rates of customs duty (tariffs) on imports into the UK set by a temporary tariff regime. Under this temporary regime, the majority of UK imports would be tariff-free. These rates would only be applied if the UK were to leave the EU with no deal and would be in place for up to 12 months. The temporary rates of customs duty on imports are listed here.

34.2. If you need to pay customs duty, the rates (tariffs) could vary depending on where you import your good from. You can find the commodity codes here.

35. Bringing goods to the UK from the EU through a roll-on, roll-off port or Channel Tunnel[20]

35.1. You will not be able to complete a customs declaration when your goods arrive in the UK, all goods will need to be declared before checking them onto the ferry or train on the EU side, no earlier than 21 days before they arrive at the EU departure port (or Eurotunnel). You will be able to change your customs declaration up until the point you check in at the departure port.

35.2. You can register to use transitional simplified procedures to: transport your goods into the UK without having to make a full customs declaration at the port; make a more detailed declaration later; defer paying your duty. Once registered, you will be able to make either: a simplified frontier declaration (electronically submitted to HMRC); or an entry in your own records of when the goods cross the border.

35.3. Once your goods have arrived in the UK, you will need to update your declaration using your software application to confirm they have arrived or have your customs agent do this for you. This will need to be completed no later than the end of the working day after the goods' arrival in the UK. For both the simplified frontier declaration and entry in your own records, you will normally have to submit a supplementary declaration by the fourth working day of the month after your goods have arrived in the UK. HMRC will inform you when this needs to be completed.

36. VAT[21]

36.1. If your business is registered for VAT in the UK, you'll be able to account for import VAT on your VAT Return. This means you will pay import VAT on your VAT Return instead of when the goods arrive at the UK border.

36.2. If you are not VAT-registered in the UK, you will not be able to account for import VAT in this way, and you'll need to pay import VAT at the time you import the goods.

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[20] HM Revenue & Customs, *Bringing goods to the UK from the EU through roll on roll off ports or the Channel Tunnel*, 4 February 2019, available at: https://www.gov.uk/guidance/moving-goods-to-and-from-the-eu-through-roll-on-roll-off-locations-including-eurotunnel

[21] HM Revenue & Customs, *VAT for businesses if there's no Brexit deal,* 30 August 2019, available at: https://www.gov.uk/government/publications/vat-for-businesses-if-theres-no-brexit-deal/vat-for-businesses-if-theres-no-brexit-deal--2

36.3. You must continue to treat goods already in transit from the EU as acquisitions and account for VAT on the return for the period in which the acquisition takes place.

36.4. If you're bringing goods into the UK under customs freight simplified procedures and you've completed your simplified frontier declaration before exit day, you will not be able to account for import VAT on your VAT Return even if you complete your supplementary declaration after this time.

36.5. You can still account for import VAT on your VAT Return, even if you cannot confirm the customs value of the goods that you import. You should declare the highest value for VAT and reclaim any eligible input tax under the normal rules.

36.6. After EU exit, you will be able to check if a UK VAT number is valid by using the UK's VAT checking service (this service is not available yet).

36.7. You'll no longer be able to use the EU's VAT number validation service, to check the validity of a UK VAT number, or use the EU VAT refund electronic system to claim refunds of VAT incurred in the UK.

Intellectual property

The EU Withdrawal Act 2018 transposed EU legislation on patents and trade marks into UK law, thereby ensuring that intellectual property continues to be protected in the UK. This includes changes to the supplementary protection certificates that provide extended IP protection for medicines. As the UK will continue to participate in the European Patent Convention, you can continue to apply to the European Patent Office for patent protection which will cover the UK.

37. Patents if there's no EU Exit deal[22]

37.1. The relevant EU legislation (or its domestic implementation) will be retained in UK law under the EU Withdrawal Act 2018, including new EU law making changes to the supplementary protection certificates system introduced since April 2019 that covers the additional period of IP protection for medicines. The existing systems will therefore remain in place, operating independently from the EU regime, with all the current conditions and requirements.

37.2. All other EU legislation relevant to patents and supplementary protection certificates will be kept in UK law. This will ensure UK law continues to work in respect of biotechnology patents and applications, compulsory licensing arrangements, and exceptions from infringement for the testing of pharmaceutical products. This means current requirements that a supplementary protection certificate can only be granted by a patent and MA in the Member State where protection is being sought still stand – ie in the UK. After exit day, this application will be made to the Intellectual Property Office and will be the same format as it was before leaving the EU.

37.3. The UK will continue to be a participating state in the European Patent Convention, since this is not an EU treaty. You can therefore continue to apply to the European Patent Office for patent protection which will cover the UK.

37.4. Any existing rights and licences in force in the UK will remain in force automatically after the UK leaves the EU and no action is required from the right or licence holder. For UK, EU and third country businesses, there will be no significant change to the legal requirements or the application processes, which can still be located in the UK, Isle of Man or the EEA.

37.5. UK, EU and third country businesses will also continue to be able to obtain a compulsory licence for manufacturing a patented medicine to meet a specific health need in a developing country. You can also continue to rely on the exceptions from patent infringement provided for trials, studies and tests carried out on a pharmaceutical product.

38. Correspondence addresses and confidentiality for UK patents

[22] Department for Business, Energy and Industrial Strategy, *Changes to SPC and patent law in the event of Brexit without a withdrawal agreement*, 26 September 2019, available at: https://www.gov.uk/government/publications/changes-to-spc-and-patent-law-if-uk-leaves-the-eu-without-a-deal/changes-to-spc-and-patent-law-if-the-uk-leaves-the-eu-without-a-deal

38.1. There will be no immediate changes to the UK address for service rules. Privilege for patent attorneys will remain unaffected as this is not determined by reference to EU membership. There will be no immediate implications for UK, EU or third country businesses. The current rules will remain in place at the point the UK exits the EU.

39. Trade mark rights[23]

39.1. After EU exit, any existing EU Trade Marks (EUTM) will only cover the remaining EU Member States, and so will not provide protection in the UK. To preserve UK protection, the UK Government will provide holders of existing EUTMs with a comparable trade mark on exit day.

39.2. UK businesses will still be able to obtain trade mark protection in the remaining 27 Member States of the EU through an application to the EU Intellectual Property Office, and business in the EU and worldwide will be able to apply for a UK domestic trade mark.

39.3. The new UK right will be provided with minimal administrative burden. The trade mark or design will then be treated as if it had been applied for and registered under UK law. This means that these trade marks and designs:

39.3.1. Will be subject to renewal in the UK;
39.3.2. Will form the basis for proceedings before the UK Courts and the Intellectual Property Office's Tribunal; and
39.3.3. Will be assigned and licensed independently from the EU right.

[23] Department of Business, Energy & Industrial Strategy, *Changes to trade mark law in the event of Brexit without a withdrawal agreement*, 19 September 2019, available at: https://www.gov.uk/government/publications/changes-to-trade-mark-law-if-the-uk-leaves-the-eu-without-a-deal/changes-to-trade-mark-law-in-the-event-of-no-deal-from-the-european-union

Horizon 2020 funding[24]

The UK Government has committed to funding all successful competitive UK bids submitted before the UK leaves the EU and those open to third-country participants submitted between leaving the EU and the end of 2020.

40. Future of Horizon 2020 funding

40.1. The UK Government has committed to guarantee funding for all successful competitive UK bids to Horizon 2020 that are submitted before we leave the EU, if there's a no-deal exit.

40.2. The guarantee also covers all successful competitive UK bids to Horizon 2020 calls open to third-country participation submitted between EU Exit and the end of 2020. Both the guarantee and extension commit funding to UK Horizon 2020 participants for the lifetime of projects.

40.3. UK Research and Innovation (UKRI) will also manage the independent assessment of UK applications to European Research Council (ERC), Marie Skłodowska-Curie Actions (MSCA) and SMEi grants that have been submitted before exit day, if they are not assessed by the European Commission. Successful applications will be funded for the lifetime of the project.

40.4. Current UK recipients of Horizon 2020 funding need to provide initial information about their projects on the UKRI portal accessible here.

[24] Department of Business, Energy & Industrial Strategy, *Horizon 2020 funding after Brexit*, 9 August 2019, available at: https://www.gov.uk/guidance/horizon-2020-funding-after-brexit

Employing EU citizens[25]

If the UK leaves the EU without a deal on 31 October 2019, there will be no changes to EU, EEA and Swiss employees' right to work in the UK until 31 December 2020. After this time, a new immigration system will be put in place. In the meantime, there are schemes that employees can apply for to continue to live in the UK after 31 December 2020, notably: the EU Settlement Scheme; and European temporary leave to remain.

41. Duty of employers

41.1. There will be no change to the right to work of EU, EEA and Swiss citizens and their family members living in the UK until 31 December 2020 if the UK leaves the EU without a deal.

41.2. Employers will need to check a job applicant's right to work in the same way as now until 1 January 2021.

41.3. A new immigration system will apply to people arriving on or after 1 January 2021. You will not be required to undertake retrospective checks on existing EU, EEA or Swiss employees.

42. EU Settlement Scheme

42.1. EU, EEA or Swiss citizens and their family members who are living in the UK before the UK leaves the EU can apply to the EU Settlement Scheme to continue living in the UK after 31 December 2020.

43. European temporary leave to remain

43.1. If EU, EEA and Swiss citizens arrive in the UK after the UK leaves the EU and before 1 January 2021, they can apply for European temporary leave to remain. The deadline for applications is 31 December 2020.

44. Travelling to the EU[26]

44.1. If the UK leaves the EU without a deal, British passport holders travelling to the EU will need to have 6 months remaining validity on their passport, not including any extra months added to a 10-year passport if it was renewed early.

[25] Home Office, *Right to work checks on EU citizens if the UK leaves the EU without a deal*, 5 September 2019, available at: https://www.gov.uk/guidance/horizon-2020-funding-after-brexit
[26] HM Passport Office, *Passport rules for travel to Europe after Brexit*, 12 April 2019, available at: https://www.gov.uk/guidance/passport-rules-for-travel-to-europe-after-brexit

Personal data

If the UK leaves the EU without a deal, there will be no immediate changes to the UK's data protection standards and the General Data Protection Regulation will still apply. However, if your organisation receives data from the EU/EEA, you will need to ensure you have Standard Contractual Clauses or other Alternative Transfer Mechanisms in place to ensure you can continue to receive this personal data.

45. .eu domain names – what members need to do[27]

45.1. If the UK leaves the EU without a deal, you will no longer be able to register or renew .eu domain names if:

45.1.1. Your organisation, business or undertaking is established in the UK but not in the EU/European Economic Area (EEA); or
45.1.2. You live outside of the EU/EEA and are not an EU/EEA citizen

45.2. You may still satisfy the eligibility criteria if you have your registered office, central administration, or principal place of business within the EU/EEA, are established within the EU/EEA, or are a natural person resident in the EU/EEA.

45.3. The European Commission and EURid have confirmed that EU/EEA citizens who are resident in the UK will be able to retain their .eu addresses. If you are an EU/EEA citizen living in the UK and have registered a .eu domain name, discuss with your registrar whether you will need to provide proof of eligibility.

46. Using personal data in your business or organisation[28]

46.1. If your organisation receives personal data from the EU/EEA, you should review your contracts and, where absent, include Standard Contractual Clauses (SCC) or other Alternative Transfer Mechanisms (ATM) to ensure that you can continue to legally receive personal data from the EU/EEA.

46.2. Businesses that are part of a multinational group may be able to rely on binding corporate rules (BCRs) for intra-group transfers as an appropriate safeguard.

46.3. If the UK leaves the EU without a deal, UK businesses and organisations will still need to be compliant with data protection law.

46.4. There will be no immediate change to the UK's data protection standards. The General Data Protection Regulation (GDPR) will be brought into UK law and the Information Commissioner would remain the UK's independent supervisory authority on data protection.

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[27] Department for Digital, Culture, Media & Sport, *.eu domain names – what you need to do if there's no Brexit deal*, 5 April 2019, available at: https://www.gov.uk/government/publications/guidance-on-eu-top-level-domain-name-registrations-in-the-event-of-a-no-deal-eu-exit

[28] Department for Digital, Culture, Media & Sport, *Using personal data in your business or organisation if there's no Brexit deal*, 6 February 2019, available at: https://www.gov.uk/guidance/using-personal-data-after-brexit

Structuring cross-border business operations[29]

If your company is UK registered but operates in the EU or EEA, you may need to check to ensure your cross-border business operations meet the relevant countries' incorporation requirements. If your company is EU/EEA registered, you may also need to share additional information with Companies House after the UK has left the EU.

47. Cross-border business operations

47.1. UK registered companies which operate in the EU should check they meet relevant EU countries' incorporation requirements. They may need to make adjustments to their structure.

47.2. UK companies with a European Economic Area (EEA) corporate appointment and EEA companies registered with Companies House will need to provide some additional information to Companies House within 3 months of exit day.

48. Cross-border mergers

48.1. UK companies using the EU Cross Border Merger regime should be at an advanced stage of the process if they are to complete mergers before EU exit. These mergers must be completed by exit day. Companies may wish to seek professional advice.

[29] Department for Business, Energy & Industrial Strategy, *Structuring your business if there's a no-deal Brexit*, 8 August 2019, available at: https://www.gov.uk/guidance/structuring-your-business-if-theres-a-no-deal-brexit

Public-sector procurement[30]

There will be minimal immediate changes to public procurement regulations if the UK leaves the EU without a deal. However, member companies may wish to register on the new e-notification service, Find a Tender.

49. Changes for businesses

49.1. If the UK leaves the EU without a deal, the public procurement regulations will remain broadly unchanged. In March 2019 the Minister for the Cabinet Office made a Statutory Instrument (SI) which will amend the procurement regulations to ensure that they continue to operate effectively after exit day. The SI will come into force on exit day.

49.2. Suppliers wishing to access UK contract opportunities from the UK public sector will need to access the new UK e-notification service, Find a Tender, instead of the Official Journal of the EU (OJEU) or Tenders Electronic Daily (TED).

49.3. Find a Tender is free, and you do not need to register to search the site, but registration will enable you to save searches, set up email alerts and "watch" notices etc. If you are already registered on Contracts Finder, your log in credentials will work for Find a Tender.

[30] Cabinet Office, *Public-sector procurement after a no-deal Brexit*, 25 September 2019, available at: https://www.gov.uk/guidance/public-sector-procurement-after-a-no-deal-brexit

Appendix: referenced guidance

Cabinet Office, *Public-sector procurement after a no-deal Brexit*, 25 September 2019, available at: https://www.gov.uk/guidance/public-sector-procurement-after-a-no-deal-brexit

Department of Business, Energy & Industrial Strategy, *Horizon 2020 funding after Brexit*, 9 August 2019, available at: https://www.gov.uk/guidance/horizon-2020-funding-after-brexit

Department for Business, Energy and Industrial Strategy, *Changes to SPC and patent law in the event of Brexit without a withdrawal agreement*, 26 September 2019, available at: https://www.gov.uk/government/publications/changes-to-spc-and-patent-law-if-uk-leaves-the-eu-without-a-deal/changes-to-spc-and-patent-law-if-the-uk-leaves-the-eu-without-a-deal

Department of Business, Energy & Industrial Strategy, *Changes to trade mark law in the event of Brexit without a withdrawal agreement*, 19 September 2019, available at: https://www.gov.uk/government/publications/changes-to-trade-mark-law-if-the-uk-leaves-the-eu-without-a-deal/changes-to-trade-mark-law-in-the-event-of-no-deal-from-the-european-union

Department for Business, Energy & Industrial Strategy, *Structuring your business if there's a no-deal Brexit*, 8 August 2019, available at: https://www.gov.uk/guidance/structuring-your-business-if-theres-a-no-deal-brexit

Department for Digital, Culture, Media & Sport, *.eu domain names – what you need to do if there's no Brexit deal*, 5 April 2019, available at: https://www.gov.uk/government/publications/guidance-on-eu-top-level-domain-name-registrations-in-the-event-of-a-no-deal-eu-exit

Department for Digital, Culture, Media & Sport, *Using personal data in your business or organisation if there's no Brexit deal*, 6 February 2019, available at: https://www.gov.uk/guidance/using-personal-data-after-brexit

Department for Environment, Food and Rural Affairs *Prepare your food and drink business for a no-deal Brexit* 20 September 2019; available at: https://www.gov.uk/guidance/the-food-and-drink-sector-and-preparing-for-eu-exit

Department for Environment, Food and Rural Affairs *Food and alcoholic drink labelling changes if there's a no-deal Brexit* 23 August 2019; available at https://www.gov.uk/guidance/food-labelling-changes-after-brexit

Department for Environment, Food and Rural Affairs; Rural Payments Agency and Animal and Plant Health Agency *Export food, drink and agricultural products* 1 October 2019; available at: https://www.gov.uk/guidance/export-food-and-agricultural-products-special-rules#prepare-for-brexit

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