Further guidance note on the regulation of medicines, medical devices and clinical trials in a no-deal Brexit

Information for stakeholders so you can make informed plans and preparations in the event of leaving the EU with no deal.

Published 3 January 2019
Last updated 8 August 2019 — see all updates

From:

Medicines and Healthcare products Regulatory Agency

Documents

Further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal

1. Medicines

1.1 How we propose to regulate medicines if there is no-deal Brexit

The UK's participation in the EMRN would cease and the MHRA would take on the functions currently undertaken by the EU for human medicines on the UK market.

It is currently an offence to sell or supply, or to offer to sell or supply, unauthorised medicines to a person within the European Economic Area (EEA) (regulation 46 HMR). After Brexit, the offence will cover sales and supplies to a person in the United Kingdom and EU/EEA.

Transitional provision in legislation will ensure that all currently granted Centrally Authorised Products (CAPs) automatically become UK MAs on exit day, although the holders will have a short period of time after exit day within which to opt out of having a UK MA. The MHRA will have oversight of all pharmacovigilance activities. Currently, risk management plans, reports of suspected adverse drug reactions from the pharmaceutical industry, the majority of periodic safety update reports (PSURs) and post-authorisation safety studies (PASS) are submitted and assessed at EU-level. Post Brexit, these will need to be submitted to and assessed by the MHRA.

1.2 Converting CAPs into UK MAs

Most human medicines on the UK market already have a UK Marketing Authorisation (MA), and this will be unaffected by our exit from the EU. However, most novel medicines and biosimilars, and some generics, come to market via the European Medicines Agency's (EMA's)

centralised MA route. Medicines approved via this route are known as CAPs.

To ensure such medicines will continue to be authorised for use in the UK, all CAP MAswill automatically be converted into UK MAs on the day the UK leaves the EU (also known as “grandfathering”). The MHRA has already written to CAP Marketing Authorisation Holders (MAHs) to inform them of the UK intention to grandfather the MAs and to explain what action they need to take and to provide information on how they will be able to opt out of receiving a UK MA, as well as providing guidance on data requirements related to grandfathering. MHRA will also write to MAHs for new CAPsapproved before Brexit.

A high-level overview of the process is that:

- MAHs will have 1 year from exit day to provide MHRA with baseline data for CAPs that are converted into UK MAs.
- In order to process any variations, MHRA will require the baseline data to have been submitted or,
- MHRA will accept a ‘basic’ baseline data set initially which will enable variations and other post-authorisation submissions to be processed. The full baseline data requirements will still need to be met within one year of Brexit.

For further inquiries on the requirements for conversion email capconversion@mhra.gov.uk.

1.3 MA assessment routes

The MHRA would offer the following new assessment procedures for applications for products containing new active substances and biosimilars alongside our existing 210-day national licensing route (which, for the time being, will continue to operate as now):

- A targeted assessment of new applications for products containing new active substances or biosimilars which have been submitted to the EMA and received a Committee for Medicinal Products for Human Use (CHMP) positive opinion, based on submission of all relevant information and the CHMP assessment reports to MHRA. The MHRA

review will be completed within 67 days of submission of the application.

- A full accelerated assessment, that industry can choose for new active substances, with a timeline of no more than 150 days.
- A ‘rolling review’, for new active substances and biosimilars, which would allow companies to make an application in stages, throughout the product’s development, to better manage development risk.

We will work with industry to identify options to reduce the current national licensing timetable from 210-days to 180 days. MHRA will also conduct a review to understand if the principles of targeted assessment could be extended to generics.

1.4 Orphan medicines

Orphan (rare disease) medicines are currently regulated through the EU system where an ‘orphan designation’ may be given during development if the criteria are met, and orphan status is re-assessed at the stage of assessing an application for an MA. Orphan products currently have access to the central EU authorisation system and if an orphan MA is granted, the product benefits from a 10-year period of marketing exclusivity from competition from similar products.

After Brexit there will be a UK system for rare disease medicinal products with orphan status determined at the point of MA as is the case in the current EU system. Overall, the orphan criteria would still be based on the current EU criteria, but UK-specifics will be incorporated. These will be based on the prevalence of the rare disease in the UK, the availability of satisfactory alternative treatment methods in the UK and the significant benefit of the product. The evaluation of compliance with orphan criteria would be conducted in parallel with the review of quality, safety and efficacy of the medicine at the time of the MA application.

Where a medicine receives orphan status the initial MA application fee will be refunded at 100% for SMEs and 10% for all other manufacturers. For these medicines SMEs will also receive a fee waiver for variations in the first year after the MA is granted.

The 10 years market exclusivity from competition from similar products in the approved orphan indication would be retained. If criteria for orphan status are met, this incentive would be awarded following grant of a UK orphan MA (see section below on Data and market exclusivity for MAs.

The EU pre-marketing authorisation orphan designation will not be replicated in the UK, given that this will be available at EU level and that a separate UK-only designation is unlikely to further incentivise industry to warrant the investment required to resource a separate system. As it has been proposed to have a UK-specific criteria for determining whether a drug qualifies as ‘orphan’, it would not be possible simply to accept the EU designation for these high value drugs; however, Government has committed to monitor these incentives and will consider any further evidence to support this.

1.5 Scientific advice for UK based SMEs

The MHRA will not charge a fee for scientific advice to any small and medium-sized enterprises (SMEs) established in the UK. This is being provided to support SMEs and help retain research and development in the UK. Further guidance on how this will be provided will be communicated in due course.

1.6 Paediatric investigation plans (PIPs) and studies

The UK is currently part of the EU system for paediatric drug development including PIPs. These are development plans aimed at ensuring that the necessary data are obtained through studies in children to support efficacy and safety. Decisions in relation to paediatric matters, such as agreeing a PIP and granting waivers and deferrals, are currently made at EU level, as well as assessments of compliance with PIPs.

In the event of no deal, the MHRA will take decisions on paediatric matters post Exit. Compliance with a UK PIP or waiver should be demonstrated in applications for new medicinal products, as well as in

new indications, new routes of administration, and new pharmaceutical forms for all products with supplementary patent protection. The same rewards for PIP compliance would be available - a 6-month extension of a UK Supplementary Protection Certificate (SPC) (an SPC extends patent protection for medicinal products), as well as 2 years' additional market exclusivity for orphan products complying with a PIP. A UK SPC will be awarded in the UK on the same basis as it is currently granted under EU legislation.

Guidance on submission of PIPs and paediatric studies will be provided in due course.

1.7 Data and market exclusivity for MAs

Data and market exclusivity in the UK will start on the date of authorisation in the UK or EU, whichever comes first. This will also apply in relation to marketing exclusivity for orphan products.

The Government will review this within 2 years of Brexit in order to make sure we remain competitive.

1.8 Legal presence requirements

There will be certain requirements around legal presence in the UK for MAHs. The requirements will be:

- A MAH should be established in the UK by the end of 2020.
- A Qualified Person for Pharmacovigilance (QPPV) should be established in the UK on day one. However, a temporary exemption will allow companies until the end of 2020 to do so. This temporary exemption will allow an EU QPPV to assume responsibility for UK MAs until a QPPV who resides and operates in the UK can be established.
- In respect of a manufacturing licence, a Qualified Person (QP) for products manufactured in the UK or directly imported into the UK from a country not on an approved country list (which will include all EU and EEA countries from Day 1) must reside and operate in the UK.

- For products imported from an approved country list (EU and EEA countries), see section on licensing regime for wholesalers importing QP certified medicines below.

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 Brexit. This individual must be accessible to the licensing authority in respect of any matter relating to the MA. This requirement will no longer apply once a UK MAH is established.

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

Further guidance on these requirements will be published in due course, including on:

- Change of Ownership applications – such applications will need to be submitted to MHRA when changing from an EU MAH to a UK MAH for UK MAs. Companies have until the end of 2020 to establish the MAH in the UK.
- The requirements of the UK QPPV.
- The process for submitting a variation reflecting a change of QPPV. If it is a Type IAIN MHRA will not charge a fee.

1.9 Licensing regime for wholesalers importing QPcertified medicines

The UK will continue to recognise QP certification from EU / EEA countries after Brexit.

However, to ensure public safety, there will be a need to distinguish between those medicines that have been QP certified in the EU/EEA and those which are passing through the EU / EEA in transit to the UK (known as ‘introduced medicines’).

To enable this, all existing holders of UK Wholesale Authorisations will be permitted to purchase medicines that have been QP certified in the

EU/EEA. If the wholesale licence holder wishes to continue this activity, they must notify MHRA within 6 months of Brexit of their intention to continue. A revised Wholesale Dealer Authorisation will be issued to include importation of medicines from countries on a list. New wholesaler applications for such a licence made after Brexit will be charged the normal fee.

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), for which guidance will follow. Wholesalers will have a 2-year period after Brexit to name a RP-I on their authorisation, but will be expected from Brexit to have assurance systems in place to avoid introduced medicines entering the UK supply chain without QP certification. Guidance on the RP-I role will follow in due course.

Wholesalers who wish to trade only with authorised manufacturers and wholesalers located in the UK may continue to do so under their existing wholesale authorisation and Responsible Person arrangements.

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

1.10 Packaging and leaflets

Some packaging and leaflets for medicinal products in the UK will have to be amended to comply with the UK requirements. The MHRA will give industry until the end of 2021 to amend certain administrative details on the packaging and in the package leaflets for a product already on the market.

These amendments include: UK administrative information such as the UK MAH's name and address, UK product licence (PL) number and up to date information about the manufacturing site. Any regulatory interventions that may impact on public health required before the end of

2021 will have to be implemented in real time. It is expected that the administrative information which requires updating as a result of relocation into the UK will be amended at the same time as any safety changes being introduced and will not be further delayed.

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

The UK is proceeding with 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, as stated in the MHRA's consultation, if there is a no-deal Brexit. it is expected UK stakeholders would no longer be able to comply with the requirement to verify and authenticate. Therefore, the legal obligations related to this would be removed for all actors in the UK supply chain.

Packs containing the Falsified Medicines Directive (FMD) safety features would still be accepted in the UK, provided that they are in line with other UK packaging requirements. In the interests of public safety, we will evaluate the options for a future UK falsified medicines regulatory framework, taking into account the investment already made by stakeholders.

1.11 Abridged applications

An abridged procedure is an application for a marketing authorisation which does not need full pre-clinical or clinical studies. The types of application that may be able to use this route are generic applications/hybrid abridged/biosimilars.

Abridged procedures for obtaining an MA in the UK would remain in place. However, they would be amended as it would not be possible to rely on a European reference product for any new applications submitted after the UK has left the EU.

New abridged applications would need to be based on reference products that have been authorised in the UK, including CAPs which have been converted to UK MAs or non-converted CAPs which were granted prior to exit day. Additional guidance on the requirements for the new applications will be published in due course.

UK MAs based on EU reference products that have been granted (or are the subject of pending applications) prior to exit day will remain valid after exit day.

UK MAs already approved on exit day in decentralised and mutual recognition procedures will remain valid in the UK.

1.12 Parallel imports

Parallel import of medicinal products is an important route of supply for medicinal products in the United Kingdom and provides cost savings to the NHS across the UK, as well as alleviating supply issues.

Medicinal products that hold a marketing authorisation in another Member State, or are CAPs, and are essentially similar to a product that has been granted a UK marketing authorisation, will still be able to be imported under a parallel import licence in the event of no-deal.

This will be subject to the MHRA being able to obtain the necessary information to show the parallel import product is indeed essentially similar to the UK reference product.

The parallel import regime will remain limited to EU and EEA countries. The MHRA will be able to vary, suspend or revoke a parallel import licence if the UK reference product is suspended, revoked or varied. It will also be able to do likewise if it can no longer be satisfied that a product to be imported remains essentially similar to the UK product: that power will not be exercised before 1 April 2020. Nor will it be exercised in respect of products that were certified for release by a qualified person in the EEA before exit day.

Parallel import licence holders will in future need to be established in the United Kingdom. Those currently holding licences will have until 31

December 2020 to effect this change if currently established elsewhere in the EU/EEA. Until they have done so, companies will be expected to put in place a UK-based contact person within 4 weeks of Brexit. This individual must be accessible to the licensing authority in respect of any matter relating to the parallel import licence. This requirement will no longer apply once a UK licence holder is established.

Holders of parallel distribution notices, issued by the EMA, in respect of CAPs will, where the UK is listed in that notice as a destination country, be automatically, and with no fee, issued with a parallel import licence, subject to providing specified information on the products to be imported to the MHRA by 21 April 2019. The legal presence requirements outlined in relation to existing parallel import licences, will also apply to those whose parallel distribution notices are converted in this way.

Any long-term national parallel import regime will be contingent on continued alignment to the regional exhaustion regime.

1.13 Recognition of Prescriptions

The UK currently recognises prescriptions from all EU/EEA countries. Following Brexit, the UK will recognise prescriptions from an approved list of countries. The list on day 1 of exit will comprise all EEA/EU countries. Recognition of these prescriptions will be subject to the following:

- As now, the ultimate decision to dispense remains with the dispenser.
- For a prescription to be eligible, the prescriber must be of equivalent professional status to a profession that is eligible to prescribe in the UK.
- As now, these prescriptions will be dispensed as private prescriptions at no cost to the NHS.

1.14 Fees

As a trading fund the MHRA charges fees to recover the costs of statutory regulation of medicines. Changes would be needed to reflect the costs of the new regulatory changes being introduced after Brexit.

The fees changes that will be introduced are:

1. fees for new targeted assessment procedures for marketing authorisation (MA) applications, 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
2. refunds of MA application fees for products granted orphan status, with 100% refund for SMEs and 10% for all other manufacturers. A fee waiver for variations in the first year after an orphan MA is granted will also be provided for SMEs
3. fees of £8,309 for certification of a new Plasma Master File (PMF); £277 for a certified annual update of a PMF involving epidemiology updates only; and £734 for a certified annual update of a PMF where there are significant changes to safety-related information
4. a fee of £8,309 for certification of a new Vaccine Antigen Master File (VAMF)
5. fees of £8,309 for assessment of a Pharmacovigilance Post-Authorisation Safety Study (PASS) protocol, and £8,309 for assessment of results of a PASS study. This mirrors the approach taken by the EU – where the fee is paid once for the assessment of the protocol and then paid again for the assessment of the results when they become available
6. a fee of £51,286 to undertake a Pharmacovigilance Major Safety Review
7. a fee of £890 for a single assessment of Pharmacovigilance Periodic Safety Update Reports (PSURs)
8. changes to Renewals fees so that all new active substances (including centrally authorised products 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 centrally authorised product ‘grandfathered’ into the UK)

9. a fee waiver for provision of scientific advice to SMEs established in the UK

Additionally, fees will be introduced for UK OMCL batch testing.

1.15 Certification of batches of immunological medicinal products or a medicinal product derived from human blood or plasma

Due to the particular risks associated with medicines produced from biological material (i.e. vaccines and products made from blood), they are currently required to be tested independently of the manufacturer by a National Control Laboratory before being allowed on the market. In the UK this is undertaken by the National Institute for Biological Standards and Control (NIBSC), as part of the wider network of OMCL. Members of this network recognise batch certification and release from other network members.

In the event the UK is no longer part of this network, we will work to put in place mutual recognition of Official Control Authority Batch Release (OCABR) batch testing with other countries. We expect both Switzerland and Israel to be in this category on day of exit (through virtue of their existing MRAs with the EU being transposed into UK equivalents) and will look to add others in due course. Where such mutual agreements exist, and where the agreement allows, the UK will continue to recognise those tests without further checks, unless a specific public health concern arises. This list of countries where a mutual agreement has been established will form a mutual recognition list.

For countries where there is no mutual recognition agreement, we will require UK certification of batches by NIBSC before the medicine can be placed onto the market. The regime would be:

- EU OCABR certificates issued prior to Brexit would be accepted by the UK, whether they have been issued by the UK or another EU OCABR laboratory.
- after Brexit the UK will take a risk-based approach to the need for additional laboratory testing. NIBSC will decide whether to rely on a paper assessment to issue the UK certificate or whether to carry out laboratory testing of the batch in the UK, taking into consideration all available data, including any certificate issued by an authority on an approved list, as well as potential risks to public health. The list of countries whose certificate would be taken into account will form an approved country list (which will include all EU/EEA countries for Day 1 of Exit)
- if testing has not been carried out by an authority on the approved country list, the UK will require full laboratory assessment

There will be new statutory fees to enable NIBSC as the UK Official Medicines Control Laboratory (OMCL) to charge for OCABR certification and testing in the UK, broadly the same as the current fees charged by NIBSC in its role as an EU OCABR laboratory.

2. Medical Devices

2.1 How we propose to regulate medical devices if there's no deal

If there is a no-deal Brexit, 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 that are currently undertaken through the EU system. This section provides further detail on how we propose the UK system would operate.

See our guidance on the regulation of medical devices in the event of a no deal scenario.

2.2 Conformity of products

For a time-limited period, we 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 and devices which currently require conformity assessment by a NB must have a valid CE certificate.

If there's a no-deal Brexit, UK-based NBs will no longer be recognised by the EU after Brexit, 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.

To support the continuity of supply of products to the UK market, we will give UK-based NBs an ongoing legal status and continue to recognise the validity of certificates that they issued prior to exit day. This will allow products covered by certificates issued by UK-based notified bodies to continue to be placed on the UK market after exit day.

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.

2.3 Clinical investigations

The UK will continue to recognise existing clinical investigation approvals – both for regulatory and ethics approvals – and there will be no need to re-apply. UK clinical investigation applications will continue to be authorised by the MHRA and ethics committees as they are presently.

2.4 Market surveillance of devices

Currently, post-market safety data is shared across all members of the European regulatory network for devices (EU, EEA, Turkey and Switzerland), and any disagreement over the marketing of a device can be escalated through regulator forums such as the Medical Devices

Coordination Group, and potentially through the European Commission and Court of Justice of the European Union (CJEU).

If there's no deal, 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 CJEU.

2.5 New EU regulations

Through the no deal statutory instrument, which will amend the Medical Devices Regulations 2002, the UK will have a regulatory system in place on 1 November 2019, which will mirror all the key elements contained in Regulations 2017/745 on medical devices (MDR) and 2017/746 on in vitro diagnostic medical devices (IVDR) and which will be brought into force in line with the transitional timetable being followed by the EU for the full application of those two Regulations.

2.6 Registration of medical devices on the UK market

After exit day, all medical devices, active implantable medical devices, in vitro diagnostic medical devices (IVDs) and custom-made devices will need to be registered with the MHRA prior to being placed on the UK market.

Given this is an extension of existing registration requirements, there will be a grace period to allow time for compliance with the new registration process as set out below:

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

Registration for custom-made devices will be in line with the risk class of the device.

The registration requirements will be as follows:

- 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
- once the MDR and IVDR fully apply (from May 2020 and May 2022 respectively), the UK will then mirror the new requirements within the legislation, which will mean individual registration of all 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. No labelling changes will be required to reflect the role of this ‘UK Responsible Person’.

3. Clinical Trials of investigational medicinal products.

3.1 How we propose to regulate clinical trials if there’s no deal

If there’s no deal, the UK’s current participation in the European regulatory network for clinical trials would end, and the MHRA would take on the responsibilities for the UK that are currently undertaken through the EU system. This section provides further detail on how we propose the UK system would operate.

3.2 Existing approvals

The UK will continue to recognise existing approvals - both for regulatory and ethics approvals – and there will be no need to re-apply.

3.3 Location of trial sponsor

The UK would require the sponsor or legal representative of a clinical trial to be in the UK or country on an approved country list which would initially include EU/EEAcountries.

As part of the no-deal consultation exercise we proposed introduction of a UK contact point; however, as a result of stakeholder feedback we recognise that if the UK needs to suspend or terminate a trial, the current legislation allows the MHRA to serve the suspension/termination notice on the sponsor or the investigator(s) who are responsible for the conduct of the trial at the relevant UK sites. Therefore, separate registration of a UK contact point is not considered necessary.

Stakeholders should note that the EU's current position is that where trials are pan EU, sponsors or legal representatives must be based in the EU. There is more information on the European Commission website.

As now, if you have any questions you can contact the MHRA's Clinical Trials Helpline on 020 3080 6456.

3.4 Regulatory requirements for running a trial

The UK's current regulatory framework, as per the 2004 Regulations, will remain in force after a no deal (but will be modified using powers under the EU Withdrawal Act (EUWA) to make sure they still work in the UK after exit).

The new EU Clinical Trials Regulation (CTR) 536/2014 will not be in force in the EU at the time that the UK exits the EU and so will not be incorporated into UK law on exit day.

The Government issued an update on the CTR during the implementation period, with a clear commitment to align where possible with the CTR without delay when it does come into force in the EU, subject to usual parliamentary approvals. Equally, in the event of no-deal the Government will re-align with the parts of the EU's CTR legislation that are within the UK's control.

3.5 Regulatory requirements for Investigational Medicinal Product (IMP) for trials

Testing and certification of IMP

For IMPs coming into the UK, the UK will recognise QP certification done in an approved country (which would initially include all EU/EEA countries). This means that stakeholders will not need to QP certify IMP in the UK, if it has already been certified in one of the countries on the approved country list. Stakeholders should note that for trials running in the EU, the EU's current position is that QP certification of IMP must be undertaken within the EU/EEA – for more information please see the European Commission website.

3.6 Import licensing

All importers of IMPs into the UK will require a Manufacturers Licence (MIA). The IMPsupply chain from EEA states will allow direct supply to clinical investigator sites. For IMPs coming from countries on the approved country list the MIA(IMP) holder will be required to put in place an assurance system to check these IMPs have been QPcertified in the EU or EEA. This assurance system must be overseen by a QP. Note, such IMPs would not require re-certification. IMPs coming from other countries would, as today, require QP certification in the UK by the MIA(IMP) holder. Third party MIA(IMP) holders already exist, who act as the importer for IMPs from existing third countries to UK Clinical Trials site.

Clinical Trials Sponsors will have 12 months after Brexit to comply with this, and MHRA will publish more detailed guidance before the UK exits the EU (i.e. before the 12 months transition begins).

3.7 Safety reporting

The UK will require sponsors to submit all UK relevant suspected unexpected serious adverse reactions (SUSAR) reports to the MHRA. The only difference is that these would need to be submitted via UK based IT systems (as the option to report via EMAsystems will no longer exist).

Annual safety reports will continue to be required to be submitted to the MHRA for all UK trials as they are now.

Information on how to register to make submissions to the MHRA in a no-deal Brexit.

Clinical trials applications

UK clinical trial applications would continue to be authorised by the MHRA and ethics committees as they are presently.

The UK ability to participate in multinational trials also will not change.

As now, clinical trials applications to the UK require the contact details of the principal investigator(s) at UK sites who are the authorised health professionals responsible for the conduct of the trial for each site.

Looking beyond the immediate term, the MHRA will be improving processes for clinical trials to enable closer working with ethics bodies and allowing a single application and a single national decision in the UK. The initial pilot work has started and would continue to be developed post-Exit.

3.8 Publishing trial results

The UK's overall intention is to align transparency provisions with those currently operating in the EU, in order to eliminate the need for companies to duplicate efforts.

In the short term, those running trials should continue to use existing and established international registries such as EudraCT (EU), ISRCTN (International Standard Randomised Controlled Trial Number) registry, ISRCTN (UK), and ClinicalTrials.gov (USA) to ensure that UK patients are aware of your trial. The UK will continue to make information about trials being conducted in the UK available to patients and clinicians via the UK Clinical Trials Gateway.

By the time the EU's new portal goes live (as part of the new CTR), the UK will have its own specific hub that would give both the UK patients and researchers a single reference point for all UK trials.

3.9 More information

We have published over 30 pieces of guidance covering medicines and medical devices.

This guidance is intended to update stakeholders on the UK's proposed arrangements for the regulation of medicines, medical devices and clinical trials.

See the full list of no deal guidance published by the MHRA.