

# MHRA EU Exit no-deal contingency legislation for the regulation of medicines and medical devices

## Overview

This consultation seeks your views on how the Medicines and Healthcare products Regulatory Agency's (MHRA) legislation and regulatory processes would have to be modified in the event of the UK not securing a deal with the EU after the UK's exit, with no Implementation Period. This consultation covers no-deal proposals on medicines, clinical trials and medical devices.

## Why we are consulting

The UK is exiting the EU on 29 March 2019. The UK and EU negotiating teams have reached agreement on the terms of an implementation period that will start on 30 March 2019 and last until 31 December 2020. With talks ongoing, we remain firmly on track to reach agreement on the Withdrawal Agreement and Future Framework in the Autumn.

However, a responsible government should prepare for all potential outcomes, including the unlikely scenario in which no mutually satisfactory agreement can be reached and that is exactly what we are doing, with this consultation forming part of these preparations.

The overall approach proposed here is for the Secretary of State for Health and Social Care and the Minister for Health, Social Services and Public Safety in Northern Ireland, acting through the MHRA, to be a stand-alone medicines and medical devices regulator, taking any decisions and carrying out any functions which are currently taken or carried out at EU-level. This would include decisions on Marketing Authorisation (MA) applications which are currently authorised through the Centralised Procedure, paediatric investigation plans and orphan status, as well as pharmacovigilance responsibilities.

The full questions list and supplementary consultation documents are available below.

[Draft SI legal text](#)

[Consultation Impact Assessment](#)

[Consultation Annex](#)

[Consultation questions full printout](#)

## Introduction

### MHRA CONSULTATION ON EU EXIT NO-DEAL PROPOSALS

#### EU Exit

The UK is exiting the EU on 29th March 2019. The UK and EU negotiating teams have reached agreement on the terms of an implementation period that will start on 30 March 2019 and last until 31 December 2020. With talks ongoing, we remain firmly on track to reach agreement on the Withdrawal Agreement and Future Framework in the Autumn.

However, a responsible government should prepare for all potential outcomes, including the unlikely scenario in which no mutually satisfactory agreement can be reached and that is exactly what we are doing, with this consultation forming part of these preparations.

#### Overview

This consultation seeks your views on how the Medicines and Healthcare products Regulatory Agency's (MHRA) legislation and regulatory processes would have to be modified in the event of the UK not securing a deal with the EU after the UK's exit, with no Implementation Period. This consultation covers no-deal proposals on medicines, clinical trials and medical devices. Following on from the publication of the technical notices, on 23 August 2018, in relation to *How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal*, *Batch testing medicines if there's no Brexit deal*, and *Submitting regulatory information on medical products if there's no Brexit deal*, this consultation also asks questions on the finer detail of how that policy might be best implemented in the event of no deal being reached.

The overall approach in no-deal is for the Secretary of State for Health and Social Care and the Minister for Health, Social Services and Public Safety in Northern Ireland, acting through the MHRA, to be a stand-alone regulator, taking any decisions and carrying out any functions which are currently taken or carried out at EU-level. This would include decisions on Marketing Authorisation (MA) applications which are currently authorised through the Centralised Procedure, paediatric investigation plans and orphan status, as well as pharmacovigilance responsibilities.

## Our approach

This consultation covers changes to four different Statutory Instruments (SIs): the Medicines for Human Use (Clinical Trials) Regulations 2004, the Medical Devices Regulations 2002 and the Human Medicines Regulations 2012 (HMRs) and the Medicines (Products for Human Use) (Fees) Regulations 2016. The changes to the latter two instruments are combined in a single SI.

Many of the changes to these SIs are of a technical nature which will remove relevant references to the EU, insert references to the UK and other similar changes. The legislation is still being drafted and we are not consulting on the exact legal texts. Rather, this consultation gives narrative on any amendments being considered, with the following principles having been applied:

- pragmatic and proportionate approach in establishing UK regulatory requirements.
  - the UK regulator's ability to take regulatory action to protect public safety.
  - minimum disruption and burden on companies as the UK exits the EU.
- In line with this approach, we are also publishing the draft legal texts that relate to the amendments being consulted on in this document.

A small number of legislative changes have been communicated in August 2018 in the Government's no deal Technical Notices, to ensure that stakeholders have as much time as possible to prepare

## Policy changes with the biggest impact on which views are sought

### Consultation information

- The consultation will run for 4 weeks and close at 23:45 on 1st November 2018. You will be asked a series of questions and are required to input your responses either by clicking the corresponding button or by typing in responses where this is appropriate.
- The policy issues we are seeking your views on are listed below and more information about every issue, background and questions are in the main consultation question pages and the Consultation Annex.

### Contents of consultation (please note each section is optional depending on what areas you are interested in responding)

#### SECTION 1 MEDICINES

- Change M1: Legal presence
- Change M2: New marketing authorisation (MA) assessment routes
- Change M3: Converting centrally authorised products (CAPs) to UK MAs (grandfathering)
- Change M4: Packaging

A: Amending packaging and leaflets for a product on the market

B: Safety Features under the Falsified Medicines Directive (FMD)

- Change M5: Paediatric investigation plans (PIPs) and studies
- Change M6: Orphan designation
- Change M7: Abridged applications
- Change M8: Increased requirements for needing a manufacturer's licence for import or a wholesale dealer's licence
- Change M9: Recognition of prescriptions
- Medicines Impact Assessment

#### SECTION 2 CLINICAL TRIALS

- Change CT1: Legal presence – clinical trials
- Change CT2: Transparency
- Change CT3: Use of designated country lists, including for legal presence and importation of investigational medicinal products
- Clinical trials Impact Assessment

#### SECTION 3 MEDICAL DEVICES

- Change D1: Registration of medical devices
- Devices Impact Assessment

#### SECTION 4 FEES

- Change F1: Fee waivers for orphan products
- Change F2: New/amended MHRA fees for six processes/services previously provided centrally by EC/EMA
- Fees Impact Assessment

#### SECTION 5 NIBSC

- Change N1: Independent UK batch testing of biological medicines and associated fees

- NIBSC Impact Assessment

## SECTION 6 IMPACT ASSESSMENT

- Further comments to support the Impact Assessment

## SECTION 7 PUBLIC SECTOR EQUALITY DUTY

- Impacts (positive or negative) of these proposals on groups with protected characteristics for the purposes of the Equality Act 2010 or on other groups of people who suffer health inequalities
- 

# Draft legal text, Impact Assessment and Consultation Annex - Please consider these before responding

[Draft SI legal text](#)

[Consultation Impact Assessment](#)

[Consultation Annex](#)

## Basic information

1 What is your name?

Name

2 What is your email address?

If you enter your email address then you will automatically receive an acknowledgement email when you submit your response.

Email

3 Are you happy for MHRA to use your email address to contact you to clarify points in your response if necessary?

Single choice radio buttons (Required)

Please select only one item

- not checked  
Yes
- not checked  
No

4 What is your organisation? If you represent a business, please indicate if you are a small or micro business (1-9 or 10-49 employees)

Organisation

## How to complete this consultation

There are 7 sections in this consultation.

The first 5 sections are Medicines, Clinical Trials, Medical Devices, Fees and NIBSC. Each of these sections is skippable depending on whether or not you wish to answer that section.

For each of these five sections there will be a page for each proposed change under no-deal, where there will be information displayed about the proposed change and you can then respond beneath whether you support the proposals and give your thoughts on them. At the end of each section, there will be a page on the Impact Assessment, where you will be able to provide any

evidence on the costs to business of the proposed changes under no-deal.

The final two sections, Impact Assessment and Public Sector Duties, will give you the opportunity to give any further thoughts on the Impact Assessment that accompanies these proposals, and whether the proposals have positive or negative impacts on groups with protected characteristics for the purposes of the Equality Act 2010 or on other groups of people who suffer health inequalities.

If you are experiencing any difficulties with the consultation, please email [euexit@mhra.gov.uk](mailto:euexit@mhra.gov.uk). If you would like a printout version of all the consultation questions, please see the attached PDF below.

The infographic below shows what MHRA are looking for in effective consultation responses

# Effective consultation responses tell us...



## WHAT

- What impact the proposal would have on you or your organisation
- What policy option you prefer
- What you would change

## WHY

- Don't just make a statement, explain your reasoning
- Explain the methodology behind your calculations or analysis
- Provide any evidence you have e.g. data, academic papers, experiences, examples
  - Provide sources for your information

## CLEARLY

- Answer the questions asked
- Summarise your key points
- Be concise e.g. bullet points
  - Highlight important information e.g. bold
- Use searchable formats e.g. Word not PDF
  - Provide contact details

**Draft legal text, Impact Assessment, Consultation Annex and full question list - Please consider these before responding**

## Medicines - Changes M1-M9

5 Do you want to complete the Medicines section of the consultation?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

## Change M1: Legal Presence

### Summary

As described in the 'How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal' Technical Notice:

1. A Marketing Authorisation Holder (MAH) would have to be established in the UK by the end of 2020. Until a UK MAH is established, the UK would require a contact in the UK. This person (MAH or interim contact person) would be responsible for taking urgent action in the event of a safety concern. The MAH would retain ultimate legal responsibility, during this period.
2. As is the case today, the UK require a Qualified Person for Pharmacovigilance (QPPV) to be responsible for delivery of a pharmacovigilance system that covers UK authorised products. Given that the EU QPPV will not have responsibility towards UK authorised products, a QPPV should be established in the UK from Exit Day. Those without a current UK presence would have until the end of 2020 at the latest to establish a presence, but would nevertheless be required to make arrangements for providing the MHRA with access to the relevant safety data related to UK Marketing Authorisations (MAs) at any time, and comply with UK inspection requirements, during this period. Companies may choose to have the EU QPPV take on responsibility for UK MAs until the UK QPPV could be established. A variation should be submitted to the MHRA to change QPPV.

### Background

- Legal presence is important in order to be able to protect public health and the ability to prosecute in enforcement cases. In the event of an adverse incident, the MHRA needs to be able to contact companies 24 hours a day, 7 days a week, 365 days a year.
- The ability to prosecute a MAH in appropriate circumstances is an important deterrent to bad practice. This must be maintained, although companies must be given time to put in place the appropriate measures to meet the requirement of having a UK MAH.
- A change of ownership will need to be submitted to the MHRA to change from an EU MAH to a UK MAH for UK MAs.
- The UK QPPV would have responsibility to ensure the conduct of pharmacovigilance in accordance with the legal requirements as to pharmacovigilance imposed on the MAH, i.e. the delivery of a pharmacovigilance system that covers UK products. The requirement for a QPPV that resides in the UK allows the MHRA to gain access to the pharmacovigilance system data and documentation applied to UK MAs, in order to maintain MHRA's supervisory role over MAH compliance with pharmacovigilance.
- It is important to note that pharmacovigilance activities can be conducted anywhere globally (this is the current situation and would continue post-Exit); the role of the UK QPPV is to supervise these activities and to ensure compliance with legal requirements in the UK.

## Relevant legal text (page 2-3)

6 Do you have any views on how the proposed transition period for UK MAH and QPPV establishment should be managed by the MHRA in order to reduce any impact or burden in terms of meeting the requirements?

MAH QPPV

## Change M2: New Marketing Authorisation (MA) assessment routes

### Summary

- The MHRA would offer the following new assessment procedures for applications for products containing new active substances alongside our existing 210-day national licensing route (which will continue to operate as now):
  1. 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.
  2. A full accelerated assessment, for new active substances, with a reduced timeline of no more than 150 days.
- We would also offer a 'rolling review', for new active substances, which would allow companies to make an application in stages, throughout the product's development, to better manage development risk.
- We would also offer national conditional MAs through the conversion of the existing EU legislative framework into UK law.
- This consultation will focus on the targeted assessment route. The targeted assessment of new applications for new chemical or new biological entities and biosimilar medicines would be based on all relevant information already submitted to the EMA and the CHMP assessment report, with a commitment to grant a licence within a timeframe of 67 days from submission of the application following the positive CHMP opinion. The only exception to this would be if the UK identified an objection relating to public health.
- New fees for MAs under a new national targeted assessment route of (see Section 4 for other fees):
  1. £62,421 for a major application for a MA for a new active substance; and,
  2. £17,330 for a complex abridged application for a MA for a biosimilar.

### Background to Targeted assessment

- This route would be for novel products containing new active substances or biosimilar medicines that have obtained a positive CHMP opinion.
- A MA applicant would be able to submit the same scientific dossier content to the MHRA as that submitted in the EMA centralised procedure along with the CHMP assessment reports. Other than certain UK specific information, such as the name of the UK MAH and UK labelling and product literature, the dossier should be as submitted to the EMA.
- The CHMP rapporteurs' assessment reports would be the primary basis of the UK review of the application, the dossier would serve as a reference and for clarification at the time of approval and over the lifecycle of the use of the product in UK.
- The applicant should provide the CHMP opinion and the iterations of the rapporteurs' assessment reports generated at days 80, 120, 180 and 210 of the procedure (which could be provided by the applicant company, if a data sharing agreement is not reached with the EMA).
- The timetable for the assessment would be such that the review includes consultation with expert advisory groups and the Commission on Human Medicines (CHM) on the draft proposal for MHRA decision, within 67 days of receipt of the application.
- The MHRA would not be seeking to repeat questions or work - it would be focusing its contribution on ensuring the quality, safety and efficacy of the product in the context of clinical use in the UK. The UK decision expects to only differ from the CHMP opinion in the situations where there is a public health concern about the risk/benefit of the product.
- The suggested fee level for targeted assessment of a major application for a MA for a new active substance has been calculated based on the understanding that the required work by the MHRA would be the same as for a major application for a new active substance under incoming mutual recognition.
- The suggested fee level for a complex abridged application for a MA for a biosimilar has been calculated based on the understanding that the required work by the MHRA would be the same as for a complex abridged application under incoming mutual recognition.

## Relevant legal text (page 4)

7 Do you agree with the proposed new targeted assessment process?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

8 Do you agree with the proposed new fees for targeted assessment? Please provide comments to support your yes/no answer.

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## **Change M3: Converting centrally authorised products (CAPs) to UK MAs – commonly referred to as ‘grandfathering’ of licences**

### **Summary**

CAPs would be converted automatically into UK MAs and issued with a UK MA number on Exit day. MAHs would be given the opportunity to opt out of conversion prior to Exit. No fee would be charged for the grandfathering process.

- MAHs would have one year from Exit day to provide the MHRA with baseline data for CAPs that are converted to UK MAs. Baseline data should be submitted before any variations can be accepted by the MHRA. Under exceptional circumstances, the MHRA would allow variations to be submitted prior to baseline data.

## Background

- The vast majority of novel human medicines in the EU are currently brought to market via a single pan-EU route, overseen by the European Medicines Agency (EMA), known as the Centralised Procedure. Medicines granted MAs via this route are collectively known as Centrally Authorised Products (CAPs).
- The MHRA would write to all CAP MAHs prior to Exit to inform them of the grandfathering process and to provide them with the opportunity to opt out of receiving a UK MA. As of 6<sup>th</sup> July 2018, there were 1,045 CAPs, which would equate to around 2,500 UK product licences once converted.
- Valid CAP MAs, whose MAHs do not opt out, would automatically be treated as UK MAs on Exit day. They would be issued with a UK MA number according to the current UK practice of consolidating all pack sizes into a single MA. MAHs would be given one year, from Exit, to provide the following data for each converted CAP:
  1. Baseline sequence (including Modules 1-5, where data is held in an electronic format). This should also include the approved full colour mock-ups of the labelling (inner and outer packaging) and the patient information leaflet.
  2. An electronic Application Form (eAF) containing structured data reflecting the product as currently authorised.
  3. Summary list of all submissions subsequent to the initial application (including variations, renewals, etc.) and the sequence numbers associated with each submission where these are in an eCTD format.
- For variations submitted to the EMA but not determined before Exit day, the MHRA expects to honour the EMA's decision, with the reserve right to reject decisions by exception. There would need to be an indication with the baseline (when it is submitted) if a variation was submitted to the EMA shortly before Exit and that has been rolled into the baseline. This would need to be indicated in a cover letter and as a line item(s) in the summary of variations.
- For variations submitted to the EMA, but not determined, before Exit day:
  - Where the variation is late in the assessment process, the MHRA expects to honour the EMA's decision, with the reserve right to reject decisions by exception.
  - Where the variation has only recently been submitted to the EMA, the MHRA expects it would need to be submitted for a separate assessment.
- The exact criteria determining the ongoing variations that can be included in the baseline are to be confirmed.
- A variation required after Exit day, must be submitted after submission of the current baseline. Under exceptional circumstances, e.g., an urgent safety variation or variation to ensure continued market availability, the MHRA would accept a variation submitted before the baseline.
- The MHRA would not require historical data to be submitted by MAHs, but the MHRA would reserve the right to request historical data be provided, in a timely manner, as and when required.
- For initial Centralised Procedures ongoing assessment in the EU at the time of Exit, the application would need to be submitted directly to the MHRA and it would undergo a targeted assessment. If the CHMP has issued an opinion by the time of Exit, the MHRA would honour the opinions that it agreed with. If not yet at the CHMP opinion phase, or in the exceptional cases where the MHRA opinion diverges on public health grounds, the MHRA would consider the application as a national MA application. The MHRA would take into account any CHMP assessment that had already taken place.
- Any new applications to the UK post-Exit would be national and the UK would not participate in the centralised procedure, mutual recognition or decentralised procedures.
- The packaging (inner and outer packaging and patient information leaflet (PIL)) for converted EU MAs would need to be updated by the end of 2021. Until that time, they would be exempted from the packaging offences only in so far as the packaging does not bear a UK Product Licence (PL) number, UK MAH, or up-to-date information about the manufacturing site. See Change M4 on packaging for more information on this.

## Relevant legal text (page 5-10)

9 Do you agree with the requirements for data provision for grandfathered CAPs?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

10 Do you agree with the proposed approach to handling variations for CAP grandfathered products?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

11 Do you envisage any problems with the proposed approach to packaging for CAP grandfathered products?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## Change M4: Packaging

### Change M4: Packaging

#### A) Amending packaging and leaflets for a product on the market

##### **Summary**

- MAHs would have additional time to amend packaging and leaflets for medicinal products on the UK market with UK administrative information that changes as a result of EU Exit.
- The UK would continue to accept shared packs for medicinal products.

##### **Background**

- We would give industry until end of 2021, i.e. an additional year after the time required to change MAH (see section M1 on legal presence), to amend packaging and leaflets for a product already on the market. The amendments should be necessary to include UK administrative information such as UK MAH name and address, UK PL number and up-to-date information about the manufacturing site. However, any regulatory intervention that impacts on public health, and would require a change to the public facing information as a result, should be accompanied by amended packaging components reflecting those changes along with the necessary administrative updates as above.
- The UK would continue to approve shared packs that include administrative information from other jurisdictions, so long as the entirety of the information complies with UK requirements.

## B) Safety Features under the Falsified Medicines Directive (FMD)

### Summary

- In a no-deal, we expect the UK would not have access to the EU central data hub, and therefore stakeholders would be unable to upload, verify and decommission the unique identifier on packs of medicines in the UK. Therefore, the legal obligation related to this would be removed for actors in the UK supply chain. Packs containing the 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 around a future national falsified medicines framework, which would inform the detail of any short or longer-term modifications.

### Background

- The EU Safety Features Regulation (Commission Delegated Regulation (EU) 2016/161) becomes directly applicable in the UK on 9 February 2019 as the UK will still be a member of the EU at that point. The regulation puts obligations on manufacturers to add safety features (unique identifiers and tamper evident seals) to certain medicines packaging and upload the unique identifier to a stakeholder managed EU data hub. Wholesalers and dispensers including pharmacies and hospitals, will then need to verify authenticity of products and decommission the unique identifiers through the hub.

## Relevant legal text (page 11-12)

12 Do you agree with the proposed approach on packaging, including the period of time proposed to allow for changes?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

13 Do you agree with the proposed approach regarding Safety Features under the Falsified Medicines Directive?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## Change M5: Paediatric investigation plans (PIPs) and studies

### Summary

- MA applications for new medicinal products (new global MAs) and applications for new indications, including paediatric indications, routes of administration and new pharmaceutical forms for products with supplementary patent protection should demonstrate compliance or partial compliance with a UK PIP or have a waiver.
- Paediatric Use Marketing Authorisations (PUMAs) in compliance with a PIP may be granted through any appropriate national licensing route and would be eligible for the usual 8 years data exclusivity and further two years' market exclusivity protection.
- Class waivers, product-specific waivers and deferrals would be possible as per existing EU system.
- Reward of a 6-month extension for a UK Supplementary Protection Certificate (SPC) (which extends the patent period) based on a UK MA that complies with a PIP and paediatric information in the Summary of Product Characteristics (SmPC)/Patient Information Leaflet (PIL) would be granted in the UK on the same basis as it is currently granted in the EU.
- There would be 2 years additional market exclusivity for orphans complying with a PIP, as at present.
- Newly completed paediatric studies would need to be submitted by UK MA holders for assessment.

### Background

- There would be a UK system of paediatric obligations and incentives as currently set in the EU Paediatric Regulation.
- Currently, the EMA makes decisions on PIPs, including modifications, deferrals and waivers. In a no-deal scenario, a PIP or waiver would need to be submitted to the MHRA for a decision on a UK PIP.
- Where an application has already been made to the EMA and a positive Paediatric Committee (PDCO) opinion has been given, the EU PIP may be adopted as the UK PIP on provision of the same information already submitted to the EMA including the EMA PDCO summary reports and PDCO opinion.
- An exception to this would be in cases relating to UK public health where a further, focused assessment is needed and would be conducted based on EU information where available. This would be particularly considered for products covering rare paediatric conditions, including medicines with paediatric only development, or medicinal products to be developed in therapeutic areas that have been identified in the UK as unmet needs. The focused assessment would include consultation with expert advisory groups and/or the CHM to ensure the proposed drug development plan agreed in the PIP for the product covers the needs and context of clinical use in the UK.
- The MHRA would check compliance with the PIP for MA applications (relying on the EMA's PDCO compliance check obtained by the applicant if applicable). The MHRA would also publish information about PIPs and paediatric MAs.
- There would be new provisions in the HMRs to mirror the rewards that are available in the EU legislation, including the 6-month extension of supplementary protection certificates (SPCs), additional 2-year market exclusivity for orphan products, as well as the possibility of obtaining a PUMA.
- The post authorisation requirements in relation to MAs where the MAH benefitted from paediatric rewards would also be included.

### Existing EU PIPs

- Agreed EU PIPs/waivers (including deferrals) before Exit day would become a UK PIP/waiver and this would need to be provided and checked at validation for the purposes of UK national applications. Subsequent EU modification decisions for the same PIP would be considered through focused assessment based on UK public health needs.

## Relevant legal text (page 13-20)

14 Do you agree with the proposal for UK paediatric investigation plans (PIPs) and newly completed paediatric studies?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## Change M6: Orphan designation

### Summary

- The EU orphan criteria would be amended so that there are UK-specific criteria (in relation to the prevalence of the rare disease in the UK and the availability of satisfactory methods in the UK and significant benefit). Overall, the orphan criteria would still be based around EU regulatory concepts and should not be overly burdensome to industry (e.g. many prevalence calculations include data from the UK in the current EU system).
- The MHRA proposes to explore retention of the most important orphan incentive – namely 10 years market exclusivity from competition from similar products in the approved orphan indication. This incentive would be conferred at the time of MA approval and the evaluation of compliance with orphan criteria would be conducted in parallel with the review of quality, safety and efficacy at the time of the MA application.
- The MHRA proposes that it would not duplicate the EU pre-approval orphan designation, rather orphan status would only be assessed at the MA application stage.

### Background

- Orphan medicinal products (those for rare diseases) are currently designated as such and all authorised centrally by the EU. Post-Exit, these will be authorised by the UK licensing authority, the MHRA. The MHRA would consider applications for orphan products and the orphan criteria would be amended so that they are UK-specific (in relation to prevalence of rare diseases in the UK and availability of satisfactory methods in the UK and significant benefit). This would occur at MA stage so that the current incentive on market exclusivity continues to be available in the UK. It is envisaged that the period of exclusivity for an orphan product would be treated as starting on the date on which the product is authorised in the UK or EU, whichever is earlier.
- UK orphan status would only be assessed and awarded at the MA application stage. Paid for scientific advice would still be available at the MHRA.
- The MHRA does not propose to duplicate the EU pre-approval orphan designation, 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 is proposed to have UK specific criteria, it would not be possible to simply copy the EU designation for these high value drugs.

## Relevant legal text (page 21-26)

15 Do you agree with the proposal to explore incentivising submission of MA applications for products intended to treat rare diseases in UK?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## Change M7: Abridged applications

### Summary

- It is proposed that the various abridged procedures to getting an MA (generic applications/hybrid abridged/biosimilars/well-established use and new combinations of existing products/consent) would remain in place, but with modifications to reflect the UK's exit from the EU. The legal basis for these applications is currently described in Articles 10 – 10c of the Directive 2001/83/EC, which in turn cross-refer to Article 6. There would be amendments to the HMRs to transpose these requirements.
- It is proposed that amendments would be made to the effect that it would not be possible to rely on a European reference product post-Exit, the reference product would have to have been authorised in the UK (this would include products which have a UK MA because they are converted EU MAs). However, for applications relying on well-established use (Article 10a), the use could continue in the UK or the EU / EEA post-Exit.
- Comparators used in bioequivalence studies for the purpose of approval of generic medicines should be authorised for the UK market, if not then the batch(es) selected for use in bioequivalence study(ies) should be shown to be representative of the product(s) authorised in the UK.

### Background

- The MHRA will not have access to the data provided in support of EU approved products. Therefore, new generic applications would need to be based on reference products that have been authorised in the UK, including CAPs that have been converted in UK MAs.
- Existing MAs for generic products which are based on a reference product authorised in the EU would remain valid.

## Relevant legal text (page 27-30)

16 Do you agree with the proposal for abridged applications?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## **Change M8: Increased requirements for needing a manufacturer's licence for import or a wholesale dealer's licence**

### **Summary**

- An existing manufacturer's licence for import (MIA) or wholesale dealer's licence would remain valid. However, it is proposed that human medicines with a UK MA, which are imported into the UK from the EU/EEA, should require a MIA post-Exit.
- The UK MIA used for importation into the UK would allow the naming of Qualified Persons (QPs) in countries that are on the relevant MHRA designated country list.
- It is proposed that a transitional provision would be put in place for those who need a different type of licence as a result of the changes.

### **Background**

- Upon the UK exiting the EU, EU/EEA countries would become third countries in relation to the UK. As a result, a manufacturer's licence for import (MIA) would be required to import human medicines into the UK from the EU/EEA. Currently, medicines manufactured in, or imported into, the EU/EEA under the control of a EU-based MIA are supplied to the UK via a UK wholesale dealer, who would hold a wholesale dealer's licence, or through direct sale from a EU wholesale dealer or manufacturer to an 'end user', e.g. a NHS trust.
- Products with a certification of registration or traditional herbal registration would have the same inspection and import requirements as for licensed medicines.

### **Relevant legal text (page 31-34)**

17 The transitional provision for this area is still be considered. Have you views on the length of time that should be allowed for organisations to obtain MIAs, and what arrangements should be put in place during that period?

Please explain your views

## **Change M9: Recognition of prescriptions**

### **Summary**

- EU and EEA countries currently mutually recognise prescriptions issued by qualified professionals in any other EU / EEA country.
- The HMRs define who is eligible to issue prescriptions that can be dispensed in the UK.
- The proposal is to continue to recognise prescriptions from countries on a designated country list post-exit. This list will initially include EU and EEA countries.

### **Background**

- At present the EU cross border healthcare directive means that prescriptions issued in any EU / EEA country can be dispensed across the EU / EEA. This directive will cease to apply to the UK in the case of no deal.
- We propose that the UK continues to recognise prescriptions from countries on a designated country list post exit, and that this list initially includes all EU / EEA countries. We propose to maintain the condition that this approach should be subject to the ability of the pharmacist to confirm professional registration of the individual prescriber with the relevant professional body if required.
- It is possible that training standards in EEA / EU countries could diverge after EU Exit. We are therefore proposing that, following EU exit, this approach should be subject to confirmation of equivalent standards in those countries on the designated country list. As now, the ultimate decision to dispense a prescription from the EU / EEA will be at the discretion of the pharmacist and the due diligence checks that they carry out.
- As is currently the case, EU / EEA prescriptions will be processed as private prescriptions and therefore at no cost to the NHS.

## **Relevant legal text (page 35)**

18 Do you agree with the proposal to enable continued recognition of prescriptions issued in an EU / EEA country?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## Impact Assessment - Medicines

The following costs have been identified for the medicines impact assessment that will need additional information from industry to quantify.

- Cost to industry in establishing a contact person, MAH and QPPV presence in the UK for those who do not already have a UK presence - this includes the cost of labour for these representatives, the cost of establishing premises for these representatives, familiarisation and administration costs to ensure these representatives are able to do these jobs.
- The labour (staff time) and administration cost for spent dealing with the MHRA additional application procedure for those who used the EMA centralised procedure previously.
- Cost of maintaining the additional UK Marketing Authorisation for those who used the EMA centralised procedure previously
- Labour costs in terms of staff time spent providing baseline data for CAPs
- Costs to businesses of maintaining their UK MA for grandfathered CAPs, including legal and administrative costs
- The administrative and manufacturing cost to industry of amending packaging to include their UK information
- Labour costs in terms of staff time, and administration costs associated with the MIA requirement for those companies that do not currently have an MIA for importing medicines with a UK MA into the UK

### Guidance for providing evidence of costs

When referring to labour costs, please provide us with the amount of the number of staff involved, staff time used for each person, and wage of the relevant staff involved (or their job title).

Do not include inflation in future costs. We assume all costs provided are in 2018 prices.

Do not include any costs already incurred as a result of the upcoming EU exit. These are sunk costs and are not costs of implementing this particular contingency legislation.

## Relevant section of Impact Assessment (pages 10-20)

19 If you have evidence to help quantify the costs to business of these proposed changes, please respond below

Please explain your answer

20 If you have any additional costs that you think have not been included, or would like to challenge the cost analysis included in the Impact Assessment, please give your views below

Please explain your answer

21 If you would like to attach any evidence to support our assessment of the impacts, including internal business evidence, research reports or data please upload here

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## Clinical Trials - Changes CT1 - CT3

22 Do you want to complete the Clinical Trials section of the consultation?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

## Change CT1: Legal presence – clinical trials

### Summary

- For clinical trials, the UK would require the sponsor or legal representative to be in the UK or country on a designated country list from Exit day. This list would initially include the EU and EEA countries.
- Where the sponsor or legal representative are not based in the UK, we propose introducing a duty on the sponsor to ensure that the chief investigator (CI) in the UK is contactable, and UK-based to provide real assistance and facilitate action if needed.

### Background

- Currently a sponsor or legal representative can be based in the UK, EU or EEA and we are seeking to preserve this position.
- As at present, the sponsor of the trial would have overall responsibility for the trial. Where neither the sponsor or the legal representative is in the UK, we are proposing that the sponsor would need to ensure a UK-based CI is contactable to provide real assistance and facilitate action if needed. To achieve this, we propose that a new obligation is placed on the trial sponsor to ensure that a UK CI is continuously available to the licensing authority. This would ensure that someone based in the UK would be available to discuss any action required in respect of the UK trial sites (e.g. trials halts, patient recalls, etc.) in order to protect patient safety and assist with its implementation at each relevant UK trial site.

## Relevant legal text (page 36-37)

23 Do you agree with the approach proposed, for a sponsor or legal representative to be established in the UK or a designated country?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

24 Do you agree with the additional requirement on the sponsor to ensure that, where both the sponsor and legal representative are not UK-based, a CI is continuously available to assist with the actioning of any relevant licensing authority or sponsor required changes to the conduct of the trial?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## **Change CT2: Transparency**

### **Summary**

To ensure continued transparency of clinical trials, in keeping with the current situation, a change would be made for there to be a provision for MHRA to publish information on UK trials, in line with what is currently published about them in the EU clinical trials register.

### **Background**

- All EU clinical trials of investigational medicinal products (IMPs) in the EU are registered, and information on the trial and a summary of results is made public in the EU clinical trials register, except for adult phase 1 trials which are considered commercially confidential. This is done via Member States supplying the EU with data on the clinical trials in their territories.
- We propose that the licensing authority is provided a power to take on the function of ensuring information on UK trials is made accessible to the public. The intention would be to align UK transparency requirements with those current used.
- Information on how a UK system would be developed and go live will be the subject of further consultation with the sector and will not be in place on Exit day.

### **Relevant legal text (page 38)**

25 Do you agree with this approach?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## Change CT3: Use of designated country lists, including for legal presence and importation of investigational medicinal products (IMPs)

### Summary

- The MHRA would develop lists of countries where activities relating to clinical trials can be performed. There would be three such designated country lists:

1. A designated country list where a sponsor or legal representative could be established.
2. A designated country list from which:

- The UK would accept the summary of product characteristics (SmPC) (in English) as an alternative to the investigators' brochure in an ethics application, where the IMP has a MA in that country.
- Products such as advanced therapy medicinal products (ATMPs) that have an MA in the designated country would not be subject to usual special provisions when used in trials in the UK.

3. Countries from which a UK MIA (IMP) holder could import IMPs that have already been certified by a QP, for which further certification would not be required in the UK (for IMPs both manufactured in or imported to that designated country).

### Background

#### Designated country list 1

- This is a list of countries where a sponsor or legal rep could be established (see CT1 for more information on legal presence). On Exit day, EU and EEA countries would be on this list.

#### Designated country list 2

- If a product has a MA in a designated country, and is used according to the terms of the MA, the applicant may submit the current version of the SmPC in place of an investigators brochure.
- MHRA can require that explicit written authorisation (rather than tacit approval) has to be given for clinical trials of certain medicinal products in the UK, e.g. ATMPs. If the product is already on the market in a designated country then this requirement would fall away as the regulator would know it has already met equivalent standards of quality, safety and efficacy as those in the UK.
- On Exit day, this list would include EU and EEA countries.

#### Designated country list 3

- It is also proposed that there will be a designated country list in respect of QPs for IMPs. This is so that there is no UK duplication of QP certification carried out in EU27 or other countries that we think have regulatory equivalence in this area. On Exit day, EU and EEA countries will be on this list.

## Relevant legal text (page 39-40)

26 Do you agree with the proposed designated country lists?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## Impact Assessment - Clinical Trials

The following costs have been identified for the Clinical Trials section of the impact assessment that will need additional information from industry to quantify.

- The transition (one-off establishing costs) and ongoing cost of having a contactable person (Sponsor or Legal Representative) in the UK for organisations who do not already have one, which would include labour and other administrative costs
- The cost of labour in terms of staff time for businesses in publishing information about clinical trials

### Guidance for providing evidence of costs

When referring to labour costs, please provide us with the amount of the number of staff involved, staff time used for each person, and wage of the relevant staff involved (or their job title).

Do not include inflation in future costs. We assume all costs provided are in 2018 prices.

Do not include any costs already incurred as a result of the upcoming EU exit.

## Relevant section of Impact Assessment (pages 21-22)

27 If you have evidence to help quantify the costs to business of these proposed changes, please respond below

Please explain your answer

28 If you have any additional costs that you think have not been included, or would like to challenge the cost analysis included in the Clinical Trials Impact Assessment, please give your views below

Please explain your answer

29 If you would like to attach any evidence to support our assessment of the impacts, including internal business evidence, research reports or data please upload here

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## Medical Devices - Change D1

30 Do you want to complete the Medical Devices section of the consultation?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

## Change D1: Registration of medical devices

### Summary

- Registration requirements would be expanded to cover all medical devices and in-vitro diagnostics (IVDs) that are placed on the UK market.
- The responsibility for registering the medical device or IVD would fall to the economic operator (e.g. an importer, distributor or manufacturer) that first 'places the device' on the UK market. This economic operator (or UK 'sponsor') would need to be established in the UK and provide a registered address. There would be a grace period to allow time for compliance, which would – at least initially – require a small administrative fee broadly in line with the current registration charge for class I devices. See section 4 for other fee changes.

### Background

- Currently, the UK relies on being part of the European devices regulatory network (EU, EEA, Turkey and Switzerland) to access relevant information on devices to support our market surveillance work. The UK also relies on other Member States to take regulatory action in relation to manufacturers and/or authorised representatives based in their country.
- In a no-deal scenario, the MHRA would continue to perform market surveillance of medical devices on the UK market. However, being outside of the European network limits our ability to access information about devices and take action where necessary. It is therefore necessary to expand the registration requirements, and for MHRA to conduct enhanced surveillance based

upon that data.

- Requiring a 'UK sponsor' to take responsibility for the marketing of the product in the UK not only provides a regular, available contact to discuss issues, but also the ability for MHRA to take enforcement action – and deter unsafe practices – if necessary.

## Relevant legal text (page 41-42)

31 Do you agree with this approach and what do you think the timetable for transition period should be?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer and also give any views on the timetable for a transition period

## Impact Assessment - Devices

The following cost been identified for the devices impact assessment that will need additional information from industry to quantify

- Costs associated with the device registration, including the labour cost of staff time to understand and complete the registration process

There will be costs associated with non-UK medical devices manufacturers having to nominate a UK 'sponsor' to place their products on the UK market. However, we assume that acting as a 'sponsor' for an overseas devices manufacturer would be cost-neutral to the sponsor. This assumes that any regulatory costs incurred by the UK 'sponsor' would be passed on to the overseas manufacturer through any commercial agreement between the two parties, allowing the 'sponsor' to reclaim the direct costs of regulatory burden. If you have any evidence to challenge this claim, please let us know.

### Guidance for providing evidence of costs

When referring to labour costs, please provide us with the amount of the number of staff involved, staff time used for each person, and wage of the relevant staff involved (or their job title).

Do not include inflation in future costs. We assume all costs provided are in 2018 prices.

Do not include any costs already incurred as a result of the upcoming EU exit.

## Relevant section of Impact Assessment (pages 23-24)

32 If you have evidence to help quantify the costs to business of these proposed changes, please respond below

Please explain your answer

33 If you have any additional costs that you think have not been included, or would like to challenge the cost analysis included in the Devices section of the Impact Assessment, please give your views below

Please explain your answer

34 If you would like to attach any evidence to support our assessment of the impacts, including internal business evidence, research reports or data please upload here

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## Fees - Changes F1-F2

35 Do you want to complete the Fees section of the consultation?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

## Change F1: Fee waivers for orphan products

### Summary

- MHRA propose to offer fee waivers for orphan products for initial marketing authorisation (MA) applications, and variations in the first year after the initial marketing MA is granted.
  - 100% fee waiver for small-medium enterprises (SMEs) (for initial MA applications, and for variations in the first year after the initial MA is granted);
  - 10% fee waiver for all other manufacturers (for initial MA applications only)

### Background

- Currently there are fee waivers from centrally authorised products coordinated by the EMA and in no-deal, we may be seeking to offer similar benefits in the UK. The Agency is exploring the potential to waive for orphan products some or all of:
  1. the proposed fee for a targeted assessment for a major application for a new active substance (£62,421 – see 1 above);
  2. the existing national fees for licensing applications (major - £92,753; abridged complex - £25,643; abridged standard - £9,402; and abridged simple - £2,564); and
  3. the existing variation fees in the first year after the initial MA is granted.
- Those organisations that are SME's would be given a 100% fee waiver from the applicable fee for an initial MA application, and the applicable variation fees in the first year after the initial MA is granted. Definition of SME for these purposes would be put into UK legislation such that it is consistent with the definition of a micro, small or medium-sized enterprise currently used, as set out in Commission Recommendation 2003/361/EC of 6 May 2003.
- All other types of organisation would be given a 10% fee waiver from the applicable fee for an initial MA application.

36 Do you agree with the proposal to consider offering new fee waivers for orphan products?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## Change F2: New/amended MHRA fees for six processes/services previously provided centrally by EC or EMA

### Summary

- In a no-deal scenario, six other processes/services currently undertaken by the EU / EMA would need to be carried out in the UK. The MHRA is therefore proposing new MHRA fees for those existing EU/EMA processes for introduction on Exit day. The proposed MHRA fee levels are based on analogous existing products/services in the MHRA's existing statutory fees tariff, and are competitive when set against the associated fees for the comparable existing EU/EMA processes/services.

### Background

- The following six MHRA fees are proposed:
  1. A fee of £8,309 for certification of a new Plasma Master File (PMF); a fee of £277 for a certified annual update of a PMF involving epidemiology updates only; and a new fee of £734 for a certified annual update of a PMF where there are significant changes to safety-related information.
  2. A fee of £8,309 for certification of a new Vaccine Antigen Master File (VAMF).
  3. Fees of £8,309 to undertake assessment of a Pharmacovigilance Post-Authorisation Safety Study (PASS) protocol, and £8,309 to undertake assessment of a PASS results.
  4. A fee of £51,286 to undertake a Pharmacovigilance Major Safety Review.

5. A fee of £890 to undertake a single assessment of Pharmacovigilance Periodic Safety Update Reports (PSURs).
  6. Amend Renewals fees so that all new medicinal products (new active substances), whether authorised nationally, or through a centralised procedure that will become a national licensed medicine from Exit day, are subject to a renewal fee of £9,682 five years after the licence was first granted.
- Further background on each of these six proposed changes is at Annex V, and see section 4 for other fee changes.
  - Additionally, the MHRA is proposing a new fee for targeted assessment of biosimilars (see narrative on targeted assessment in Section 1, change M2), and for UK OMCL batch testing (see Section 5, change N1).

## Annex V (page 11-13)

37 Do you agree with the proposed new/amended MHRA fees for six processes/services previously provided centrally by EC/EMA?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## Impact Assessment - Fees

The following costs have been identified for the medicines impact assessment that will need additional information from industry to quantify.

- The labour and administration cost in terms of staff time to business of familiarisation with the new MHRA processes and the ongoing labour cost of completing these processes for those who previously used only the EC/EMA processes.

### **Guidance for providing evidence of costs**

When referring to labour costs, please provide us with the amount of the number of staff involved, staff time used for each person, and wage of the relevant staff involved (or their job title).

Do not include inflation in future costs. We assume all costs provided are in 2018 prices.

Do not include any costs already incurred as a result of the upcoming EU exit.

### **Relevant section of Impact Assessment (pages 25-26)**

38 If you have evidence to help quantify the costs to business of these proposed changes, please respond below

Please explain your answer

39 If you have any additional costs that you think have not been included, or would like to challenge the cost analysis included in the Impact Assessment, please give your views below

Please explain your views

40 If you would like to attach any evidence to support our assessment of the impacts, including internal business evidence, research reports or data please upload here

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### **NIBSC - Change N1**

41 Do you want to complete the NIBSC (biological medicines) section of the consultation?

Single choice radio buttons

Please select only one item

- not checked
- Yes

- not checked  
No

## **Change N1: Independent UK batch testing of biological medicines and associated fees**

### **Summary**

- A new power in the HMRs would enable the licensing authority to require UK certification of batches (immunological medicinal products or a medicinal product derived from human blood or plasma) requiring batch testing by the National Institute for Biological Standards and Control (NIBSC), and a prohibition on sale or supply until such testing takes place. However, the UK may decide on a risk-based approach to waive the associated laboratory testing for some products/batches and replace it with a paper-based assessment of data.
- EU Official Control Authority Batch Release (OCABR) certificates issued prior to 29 March 2019 would be accepted by the UK, whether they have been issued by the UK or another EU OCABR laboratory.
- There would be a new statutory fee 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.

### **Background**

- In a no deal scenario, NIBSC, as the UK's OMCL would no longer be part of the EU OCABR network, unless an agreement is reached between the UK and the EU for NIBSC to continue full membership of the OCABR network. In a no deal scenario, with NIBSC no longer part of the EU OCABR network, industry would need to apply to NIBSC for batch testing certification and associated lab testing.
- Batches of biological medicines used in the UK after 29 March 2019 would either have been certificated prior to 29 March 2019 by an EU OCABR laboratory, or by the UK National Control Laboratory on or after 29 March 2019.
- However, the UK may decide to waive the associated laboratory testing for some products/batches and replace it with a paper-based assessment of data. This would be done using a risk-based approach where such testing has already occurred within an EU OMCL. Waivers will state that the UK reserves the right to request testing of specific batches if there is a public health imperative, for example, particular product characteristics and/or test method variability. UK-specific products/batches would normally require UK test and certification.
- Individuals/organisations would be subject to
  1. A laboratory testing fee, unless the UK has issued a certificate for the batch based on a paper-assessment of the data.
  2. A mandatory certification fee to cover the administrative costs to NIBSC of issuing a batch testing certificate for the human medicinal product.
- NIBSC has developed fee proposals for batch testing certification and associated lab testing which are broadly the same as the existing NIBSC batch testing fees tariff but adapted to reflect a post-Exit no-deal environment. In summary, NIBSC is proposing three fee bands for certification, and seven fee bands for lab testing. These proposed fee bands are detailed in the table below, together with the existing NIBSC batch testing fees tariff.

## **NIBSC fee table and relevant legal text (pages 43-45)**

42 Do you agree that, as a standalone national control laboratory, NIBSC certifies batches of biological medicines used in the UK, taking a risk-based approach and accepting evidence of testing by an EU 27 OMCL as discussed above?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

43 Do you agree with this proposal for NIBSC OMCL batch testing fees?

Single choice radio buttons

Please select only one item

- not checked
- Yes
- not checked
- No

Please explain your answer

## **Impact Assessment - NIBSC**

The following costs have been identified for the medicines impact assessment that will need additional information from industry to quantify.

- The cost of staff time and administration costs of familiarisation and completion of new NIBSC requirements

### **Guidance for providing evidence of costs**

When referring to labour costs, please provide us with the amount of the number of staff involved, staff time used for each person, and wage of the relevant staff involved (or their job title).

Do not include inflation in future costs. We assume all costs provided are in 2018 prices.

Do not include any costs already incurred as a result of the upcoming EU exit.

## **Relevant section of Impact Assessment (pages 27-28)**

44 If you have evidence to help quantify the costs to business of these proposed changes, please respond below

Please explain your answer

45 If you have any additional costs that you think have not been included, or would like to challenge the cost analysis included in the Impact Assessment, please give your views below

Please explain your answer

46 If you would like to attach any evidence to support our assessment of the impacts, including internal business evidence, research reports or data please upload here

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## Impact Assessment - Further Comments

Please give any further comments, including on Impact Assessment areas not already covered, such as

- Small and micro business assessment
- Indirect costs - such as the possible passing the increased costs of regulation to purchasers of medicines
- Public health impacts
- Risks - including the desirability for business of applying to MHRA in a standalone scenario where previously European processes were used, and the ability of business to prepare for a no-deal scenario

Please also leave any questions you have about the impact assessment, including if you would like to challenge our analysis.

## Impact Assessment document

47 If you have any further comments about the content and analysis in the Impact Assessment, please provide them below.

Please give your views

## Public Sector Equality Duties

48 Do you foresee any impacts (positive or negative) of these proposals on groups with protected characteristics for the purposes of the Equality Act 2010 or on other groups of people who suffer health inequalities? If so, do you have any suggestions for mitigating negative impacts?

Single choice radio buttons

Please select only one item

- not checked  
Yes
- not checked  
No

Please explain your answer

## Any further questions or comments on this consultation?

Please give any further comments below.

49 Please give any comments or questions below

Please explain your views