**MHRA catalogue of finalised regulatory flexibilities**

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# Introduction

* MHRA is working closely with the Department of Health and Social Care (DHSC) and other healthcare partners and stakeholders to rapidly identify where flexibilities in the regulation of medicines and medical devices may be possible. This is with a view to supporting the healthcare products supply chain and wider response to the coronavirus (COVID-19) outbreak in the UK.
* This document reflects **all** regulatory flexibilities agreed and published on the MHRA website. Link: <https://www.gov.uk/guidance/mhra-regulatory-flexibilities-resulting-from-coronavirus-covid-19>
* EU regulatory flexibilities agreed and published have been grouped into the following areas:
  + Clinical trails
  + Marketing authorisations
  + Pharmacovigilance
  + Inspections and good practice
  + Blood components for transfusion
  + Medical devices.
* A summary assessment of UK regulatory flexibilities against EU emerging flexibilities has been conducted within each area.

# UK regulatory flexibilities agreed to date and published

## Overview

All UK regulatory flexibilities agreed and published are on the MHRA website.

**Link:** <https://www.gov.uk/guidance/mhra-regulatory-flexibilities-resulting-from-coronavirus-covid-19>

Making use of MHRA published regulatory flexibilities

* These flexibilities do not displace or diminish any other obligations applicable to the relevant products. Any medicinal product which benefits from these regulatory flexibilities remains subject to marketing authorisation.
* Requirements set out for each of the regulatory flexibilities may vary (for example, pre-conditions and notifications). Manufacturers should take great care to meet the relevant requirements and must satisfy themselves that the product remains safe to use before putting a flexibility in place.
* None of these flexibilities amount to authorisation or a recommendation by the MHRA for the purposes of Regulations 174 and 345 of the Human Medicines Regulations.
* These regulatory flexibilities are:
  + temporary and will be kept under review
  + offered to protect people’s health in exceptional circumstances
  + effective immediately

## Clinical trials

**Scientific advice and reviews (published 1 April 2020)**

We are providing expedited scientific advice, and rapid reviews of clinical trials applications to support manufacturers and researchers on potential treatments for COVID-19.

**Clinical Trials Unit/Good Clinical Practice (published 1 April 2020)**

We have published guidance covering [how to manage clinical trials during COVID-19](https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19).

## Marketing authorisations

**Nitrosamine responses (published 1 April 2020, updated 7 May 2020)**

In response to review under Article 5(3) of Regulation 726/2004 the deadline for [provision of step 1 nitrosamine responses will be extended](https://www.gov.uk/guidance/medicines-marketing-authorisation-holders-submission-of-nitrosamine-risk-evaluation)for an additional 6 months i.e. until 1 October 2020.

**QP Declarations (published 16 April 2020)**

COVID-19 is considered to be an exceptional circumstance for QP declarations.

EMA (European Medicines Agency) guidance (EMA/196292/2014) states:

“Exceptional circumstances, when an on-site audit is not practical (e.g. atypical actives), are out of scope of the declaration template. An off-site, remote or “paper-based” audit may be justifiable …on a case-by-case basis.”

“In these cases, a suitable quality system is expected to be applied by the active substance and finished product manufacturers. As a principle, such controls must provide confidence that the active substance is fit for purpose and will not negatively affect the safety and efficacy of the medicinal product. The QP is expected to justify the controls in place on a scientific basis and record a risk assessment on a product specific basis.”

“Audits of each site…at regular intervals…normally within three years. Justification should be provided if the date since the last audit exceeds this.”

**Variations and initial applications for products required to maintain continuity of supply (published 16 April 2020)**

We will where justified:

* Strongly encourage off-site auditing to review data/documents where possible
* Allow the re-audit window to be extended up to 4 years
* Allow the re-audit window to be extended up to 5 years where supported by an off-site audit
* Allow absence of initial onsite audit where supported by an off-site audit. If the manufacturing site has an EU GMP certificate (or appropriate certification/inspection status from a territory with which the UK/EU shares an [appropriately scoped MRA](https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/mutual-recognition-agreements-mra) or is an [EU “white listed” country](https://ec.europa.eu/health/international_cooperation/pharmaceuticals/Importation_activesubstances_en)) then this should be stated together with any appropriate supporting data.
* Other exceptional circumstances may be referred to the MHRA Regulatory Information Service for consideration on a case-by-case basis.

**30-day limit for Type 1B variation replies (published 8 April 2020)**

Suspending the 30-day limit for replies to question on [Type 1B variations](https://www.gov.uk/guidance/medicines-apply-for-a-variation-to-your-marketing-authorisation#minor-variations)

**DCP (Decentralised Procedure) CMS (Concerned Member State) applications (published 8 April 2020)**

Extending the [30-day national phase for DCP CMS applications](https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk). If requested by the company, we will hold the application with the clock off until all documentation is available.

**Leaflet mock-ups (published 8 April 2020)**

Waiving the [requirement for leaflet mock-ups to be submitted](https://www.gov.uk/guidance/medicines-apply-for-a-variation-to-your-marketing-authorisation#revised-labels-leaflets-andor-packaging) to support variations. Text versions will be accepted and these will be uploaded onto the [MHRA Products website](https://products.mhra.gov.uk/). This does not apply to 61(3) applications.

**Over-labelling (published 8 April 2020, updated 7 May 2020)**

Considering derogations from labelling requirements and over-labelling of foreign language packs for UK market on a case-by-case basis.

**Implementation period for label/leaflet changes (published 8 April 2020)**

Extending the permitted implementation period for label/leaflet changes following a variation from 6 months to 9 months. This does not apply for any significant safety updates.

**Expedited assessment of variations and initial applications (published 1 April 2020)**

We are implementing priority and expedited assessment for national variations (including batch-specific variations) and [initial marketing authorisation applications](https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk) that impact the medicines supply chain.

Guidance is in preparation on how to highlight these at the time of submission.  Please send notification of requests to expedite to MHRA in advance of submission:

* For variations: [variationqueries@mhra.gov.uk](mailto:variationqueries@mhra.gov.uk)
* For marketing authorisations: [RIS.NA@mhra.gov.uk](mailto:RIS.NA@mhra.gov.uk)

## Pharmacovigilance

**Relaxation of risk minimisation measures (published 7 May 2020, updated 19 May 2020)**

Offering urgent review procedure for industry proposals for a temporary relaxation of risk minimisation measures where they place an unnecessary burden on the NHS or shielded patients during the pandemic. This may involve assessment of complex issues and the risk. The benefit balance will need to be reviewed on a case by case basis, with patient safety the top priority.

As an example we have agreed that pregnancy testing as part of a pregnancy prevention plan (PPP) can be done remotely, on a case by case basis and when necessary, as long as the following minimum criteria are met:

* Adequate instruction and support are provided, including where possible supply of the test and a spare or, if this is not possible, provision of a list of acceptable test kits
* The pregnancy tests meet the minimum required sensitivity (25 mIU/mL)
* The result of each pregnancy test is verified by the prescriber, ideally by sending a photograph of the test result. Where this is not possible it should be verified through discussion on the telephone of the result, the kit make, and how it was used.

Where you consider that it is appropriate to use this can you please contact us at [pharmacovigilanceservice@mhra.gov.uk](mailto:pharmacovigilanceservice@mhra.gov.uk) to discuss before applying this flexibility.

**Flexibility in reporting requirement for ICSRs (published 7 May 2020)**

Agreeing with the prioritisation for ICSRs published by the Joint EU Commission, EMA and HMA Questions and answers on regulatory expectations for medicinal products for human use during the COVID-19 pandemic, however requesting that a further category is added at second on the prioritisation list, as follows: ‘submission of other serious ICSRs which reference an impact of the pandemic’ (for example, use of other medicines impacted by COVID-19).

**ICSRs (Individual Case Study Reports) (published 16 April 2020)**

Follow-up procedures, as outlined in GVP module VI, [GVP module VI](https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices#final-gvp-modules-section) should be conducted in a risk-proportionate manner and minimise the burden on health care professionals (HCPs), wherever possible.

Prioritisation should be given to:

* align to serious ICSRs
* monitored events of special interest as per the risk management plan
* prospective reports of pregnancy
* those considered important in relation to COVID-19

**Risk minimisation measures to ease burden on HCPs (published 16 April 2020)**

Waive requirement for evidence of receipt of risk minimisation measures by HCPs.

Flexibility in timelines for surveys on the effectiveness of educational materials involving HCPs.

**Postponement of other pharmacovigilance requirements (published 16 April 2020)**

Postpone or waive requirement of submission of PSURs for actives authorised only in UK, that is those not on the EURD list. Submission frequencies/dates can be amended accordingly.

**Safety variations (published 16 April 2020)**

Allow flexibility over submission of national variations/implementation dates (up to 3 months extension) for updates to product information following safety reviews, except for significant public health issues where MAHs will be advised of timelines.

Allow flexibility in accepting extension requests for RFI responses and flexibility to labels and leaflets. This is in terms of waiving requirements to submit mock-ups as part of a variation and extension of the permitted implementation period for label/leaflet changes, following a variation from 6 months to 9 months, with the exception of significant public health issues.

**Renewals (published 16 April 2020)**

Flexibility in submission date with no automatic lapse of national MAs due to lack of submission of a renewal application.

**Other areas (published 16 April 2020)**

Flexibility in allowing dissemination of Professional Communications (DHPCs) via email rather than sending hard copies.

Flexibility in allowing dissemination of educational materials via email rather than sending hard copies.

## Inspections and good practice

**Our guidance on flexibilities in this area (published 1-21 April, updated 27 May 2020)**

* We have published guidance on [exceptional GMP flexibilities for medicines manufacturers](https://www.gov.uk/guidance/exceptional-gmp-flexibilities-for-medicines-manufacturers-during-the-coronavirus-covid-19-outbreak)
* We have published guidance on [approval of GxP documents when working from home](https://www.gov.uk/guidance/approval-of-gxp-documents-when-working-from-home-during-the-coronavirus-covid-19-outbreak)
* We are allowing alternative courses of actions for [manufacturing or GxP laboratory equipment](https://www.gov.uk/guidance/guidance-for-manufacturers-and-good-practice-gxp-laboratories-on-exceptional-flexibilities-for-maintenance-and-calibration-during-the-coronavirus-co)
* We have issued [exceptional flexibilities on good distribution practice (GDP)](https://www.gov.uk/guidance/exceptional-good-distribution-practice-gdp-flexibilities-for-medicines-during-the-coronavirus-covid-19-outbreak) to support wholesalers
* [Routine inspections approach](https://www.gov.uk/government/news/new-arrangements-for-mhra-good-practice-gxp-inspections-due-to-coronavirus-covid-19--2) – we are no longer routinely undertaking onsite inspections which are being replaced with desk-based inspections in most cases
* Specials’ licence holders – We are [permitting the ‘pack down’ of large packs of licenced medicinal products](https://www.gov.uk/guidance/guidance-for-manufacturers-specials-licence-holders-on-packing-down-medicines-during-the-coronavirus-covid-19-) into smaller quantities for retail sale by pharmacies
* Imported products (3rd countries) – We [may implement reduced re-testing](https://www.gov.uk/guidance/exceptional-gmp-flexibilities-for-medicines-imported-from-third-countries-during-the-coronavirus-covid-19-outbreak) where this will significantly delay Qualified Person (QP) certification and batch release (e.g. sterility tests)

**How manufacturers and wholesalers should notify us when using flexibilities (published 21 April 2020)**

A dedicated email address has been created for manufacturers and wholesalers to notify the MHRA when using flexibilities. Notifications should be sent to [Covid19.GMDP@mhra.gov.uk](mailto:Covid19.GMDP@mhra.gov.uk) on a ‘do and tell’ basis.

No prospective MHRA approval is necessary.

The information required is:

* Manufacturing authorisation number and site number
* A description of the regulatory flexibility used
* The reason for using the flexibility
* The anticipated duration of using the flexibility, as date range or ‘ongoing’ if unknown.
* The product name and marketing authorisation number to which the flexibilities are applied (manufacturers only)
* The market to be supplied (if not UK), including confirmation that the competent authority of that market has been notified and no objection has been received.

**QP certification (published 1 April 2020)**

We will prioritise variations to add replacement QPs to MIA/MIA(IMP), including non-practising or retired QP. QP remote working arrangements will be permitted, where procedures facilitate this approach

## Blood components for transfusion

**Flexibilities for hospital blood banks (Published 3 April 2020)**

We are offering [temporary regulatory flexibility](https://www.gov.uk/guidance/information-for-hospital-blood-banks-during-the-coronavirus-covid-19-outbreak) to hospital blood banks to help them focus on service continuity during the COVID-19 outbreak

## Medical Devices

**Audits (published 5 June 2020)**

Where feasible, audits of Notified Bodies and manufacturers have been delayed. Remote audits and reviews are being considered as alternatives.

**Clinical investigations (published 2 April 2020, updated 7 May 2020)**

We have developed an [expedited process for Clinical Investigations (CIs) directly relating to COVID-19](https://www.gov.uk/guidance/medical-devices-clinical-investigations-during-the-coronavirus-covid-19-outbreak).

We will maintain a flexible and pragmatic approach to the regulatory requirements for clinical investigations.

Any amendments to existing clinical investigations as a direct result from COVID-19 will be expedited

Any new submissions for clinical investigations that will have a direct impact on the COVID-19 emergency will be processed through an expedited review

Protocol deviations as a result of COVID-19 do not need to be notified to MHRA; however you should maintain good records of these deviations. Unless there is an impact onto patient safety, you do not need to notify MHRA of COVID-19 related deviations. However, all other [protocol deviations must be reported to us as normal](https://www.gov.uk/guidance/medical-devices-clinical-investigations-during-the-coronavirus-covid-19-outbreak)

**Optimised derogations (published 2 April 2020)**

We continue to review and streamline the derogation process. The focus is primarily on critical care devices, COVID-19 testing and personal protective equipment (PPE).

We have engaged with partners to establish clear paths of communication and develop streamlined processes but equally ensure there is appropriate regulatory rigour, where required.

Our aim is to reduce the assessment timeframes significantly and to ensure the process is agile enough to rapidly respond to requests.

Further detail is outlined by our [exemptions from Devices regulations during the COVID-19 outbreak](https://www.gov.uk/guidance/exemptions-from-devices-regulations-during-the-coronavirus-covid-19-outbreak).

**Expedited advice service for devices (published 2 April 2020)**

All COVID-19 enquiries are being prioritised ahead of the Agency’s standard targets.

**Exceptional use applications (published 2 April 2020)**

[Exceptional use applications are being processed](https://www.gov.uk/guidance/exemptions-from-devices-regulations-during-the-coronavirus-covid-19-outbreak) to ensure a continued supply of non-CE Marked Medical Devices where there is a significant clinical need and where there are no CE Marked Devices available.

New specifications (published 2 April 2020)

We have issued [specifications for CPAP and ventilators](https://www.gov.uk/government/collections/mhra-guidance-on-coronavirus-covid-19#medical-devices) to ensure a continued supply of these critical medical devices during the COVID-19 crisis.

[MHRA guidance on coronavirus (COVID-19)](https://www.gov.uk/government/collections/mhra-guidance-on-coronavirus-covid-19).

# EU regulatory flexibilities agreed to date and published

## Published information

**Source 1**: EMA QUESTIONS AND ANSWERS ON REGULATORY EXPECTATIONS FOR MEDICINAL PRODUCTS FOR HUMAN USE DURING THE COVID-19 PANDEMIC. (Revision 2 –26 May 2020.)

Revision 2 – 26 May 2020



Revision 1 – 17 April 2020

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Link to live document: <https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf>

**Source 2**: MDCG 2020-4 Medical Device Coordination Group Document Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions. (Publication April 2020.)

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Link to document: <https://ec.europa.eu/docsroom/documents/40705/attachments/1/translations/en/renditions/native>

**Source 3:** EMA Nitrosamine impurities.

Link to webpage: <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities>

**Source 4**: EMA GUIDANCE ON THE MANAGEMENT OF CLINICAL TRIALS DURING THE COVID-19 (CORONAVIRUS) PANDEMIC. (Revision 3 – 28 April 2020.)



Link to document: <https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf>

Clinical trials authorisation is a national competence and 26 Member States have published national guidance to complement the EU Commission/EMA/HMA guidance

Link to individual guidance: <https://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2020_03_CTFG_Link_to_National_guidance_on_CT_managmant_during_the_COVID-19_pandemia.pdf>

**Source 5**: POINTS TO CONSIDER ON IMPLICATIONS OF CORONAVIRUS DISEASE 5 (COVID-19) ON METHODOLOGICAL ASPECTS OF ONGOING CLINICAL TRIALS (Draft, 25 March 2020)



Link to document: <https://www.ema.europa.eu/en/documents/scientific-guideline/points-consider-implications-coronavirus-disease-covid-19-methodological-aspects-ongoing-clinical_en.pdf>

(UK has provided comments to the consultation on the draft)

**Source 6**: EUROPEAN COMMISSION - COMMUNICATION FROM THE COMMISSION

Guidelines on the adoption of Union-wide derogations for medical devices in accordance with

Article 59 of Regulation (EU) 2017/745 (2020/C 171/01). (Revision 1- 19 May 2020)



Link to document: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0519(01)&from=EN>

**Source 7**: CMDh - PROCEDURAL GUIDANCE DURING COVID-19 PANDEMIC. Template for submission of an application for a Covid-19 emergency change management process (ECMP) (May 2020).



Link to webpage: <https://www.hma.eu/621.html>

Link to document: <https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/COVID-19/CMDh_420_2020_Rev.0_05_2020_-_Template_for_ECMP_applications.docx>

## Clinical trials

Source 4

Source 5

## Marketing authorisations

Source 1:

* Exceptional change management process (ECMP) Procedure [Section 2]
* Quality Variations [Section 3]
* Product Information And Labelling [Section 5]

Source 3:

* Extended deadline for response to step 1 of nitrosamine review

Source 7

## Pharmacovigilance

Source 1:

* Renewals [Section 1]
* Individual Case Safety Reports (ICSRs) reporting into Eudravigilance [Section 4]

## Inspections and good practice

Source 1:

* Use of remote QP audits for investigational medicinal products [Source 1 Section 2.5iii]
* Automatic extension of EUDRAGMDP validity dates falling due in 2020 [Source 1 Section 2.2 and 2.4]
* Distant assessment procedure [Source 1 Section 2.2]
* Remote certification by QP’s [Source 1 Section 2.5i]
* Existing arrangements that permit desktop assessments for audits supporting the QP declaration and QP batch certification of IMP’s manufactured in a third country will also be confirmed in a Q&A [Source 1 Section 2.5ii]
* Introduce new lines or new premises with limited prospective qualification [Source 1 Section 6.2i]
* Perform concurrent process validation for medicines used in treatment of COVID19 patients [Source 1 Section 6.2ii]
* Temporary changes to scheduled quality related tasks to free resources towards critical medicines used for treatments of patients infected with COVID19 [Source 1 Section 6.3 and 6.7]
* Postponing / waiving testing in a third country [Source 1 Section 6.4i]
* Postponing re-testing on importation into the EEA for medicines used in the treatment of COVID19 patients [Source 1 Section 6.4ii]
* Remote working of an RP [Source 1 Section 6.5i]
* Delegation of duties and responsibilities of an RP to another RP in the same group of companies [Source 1 Section 6.5ii]
* Delegation of RP duties to a person who is not an RP [Source 1 Section 6.5iii]
* Replacement of RP at short notice [Source 1 Section 6.4iv]
* Use of new equipment / premises for storage and distribution with limited qualification [Source 1 Section 6.6]

## Blood components for transfusion

None.

## Medical Devices

Source 2:

* Notified body audit easements

Source 6:

* Adoption of Union wide derogations for medical devices

## Human plasma for fractionation

Source 1:

* Distant assessment procedure and use of ‘statement of next inspection’ [Source 1 Section 2.3]

# Summary assessment of UK regulatory flexibilities against EU emerging flexibilities

For each of the main areas of regulatory flexibilities made available, headline flexibilities have been detailed and reviewed against those issued by the EU to assess flexibilities that:

* + align with the UK
  + are standalone
  + differ between the EU and the UK
  + align with the UK, UK aims to further.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Regulatory Flexibility** | **Align with the UK** | **Are standalone** | **Differ between the EU and the UK** | **Align with the UK, UK aims to further** |
| Clinical trials | | | | |
| Initiating New Trials  [Source 4] | Yes |  |  |  |
| Changes to Ongoing Trials  [Source 4] | Yes |  |  |  |
| Safety Reporting  [Source 4] |  |  |  | Yes – UK has some further risk proportionate provisions |
| Risk Assessment  [Source 4] | Yes |  |  | Yes – UK required confirmation that Phase I trials in accredited units had undergone a risk assessment |
| Communication With Authorities  [Source 4] |  |  |  | Yes (UK guidance deals within individual sections rather than stand alone. UK allows for greater flexibility on when a SA is needed, for example remote SDV and direct distribution of IMP to subjects homes) |
| Agreement With And Communication Between Sponsors, Trial Sites And Trial Participants  [Source 4] | Yes – although implicit in MHRA guidance across several sections |  |  |  |
| Changes To Informed Consent  [Source 4] | Yes (MHRA and HRA guidance) |  |  | MHRA and HRA have joint guidance on electronic consent |
| Changes In The Distribution Of The Investigational Medicinal Products  [Source 4] | Yes (EU provides additional guidance on re-distribution but this is in accordance with current practice).  EMA adds some detail on protection of participant personal details |  |  |  |
| Changes In The Distribution Of In Vitro Diagnostic And Medical Devices  [Source 4] |  | Not covered in MHRA guidance but EU basically is to maintain “appropriate stock” |  |  |
| Changes to Monitoring  [Source 4] | Yes |  |  | MHRA has published guidance on risk-based monitoring and this link is provided in the published COVID19 guidance  MHRA includes more guidance on remote access to EHRs |
| Changes to Auditing  [Source 4] | Yes (as part of wider guidance) |  |  |  |
| Protocol Deviations  [Source 4] | Yes |  |  |  |
| Reimbursement of Exceptional Expenses  [Source 4] |  | Not covered in MHRA guidance |  |  |
| Initiation of New Trials Aiming To Test New Treatments For Covid-19  [Source 4] |  |  | UK does not include recommendation to apply via VHP |  |
| Marketing authorisations | | | | |
| Exceptional change management process (ECMP) Procedure  [Source 1 Section 2] | X  (for national and MR/DC products) |  |  |  |
| Quality Variations  [Source 1 Section 3] |  |  |  | X |
| Labelling and Packaging  [Source 1 Section 5] | X |  |  |  |
| Extended deadline for response to step 1 of nitrosamine review  [Source 3] | X |  |  |  |
| Pharmacovigilance | | | | |
| Individual Case Safety Reports (ICSRs) reporting into Eudravigilance  [Source 1 Section 4] |  |  |  | X MHRA has also asked that submission of serious reports which reference an impact of the pandemic are also prioritised. |
| Renewals  [Source 1 Section 1.2] | X  (for national products. For CAP and MR products follow EU guidance) |  |  |  |
| Inspections and Good Practice | | | | |
| Use of remote QP audits for investigational medicinal products  [Source 1 Section 2.5iii] | X |  |  |  |
| Automatic extension of EUDRAGMDP validity dates falling due in 2020  [Source 1 Section 2.2 and 2.4] | X |  |  |  |
| Distant assessment procedure  [Source 1 Section 2.2] | X |  |  |  |
| Remote certification by QP’s  [Source 1 Section 2.5i] | X |  |  |  |
| Existing arrangements that permit desktop assessments for audits supporting the QP declaration and QP batch certification of IMP’s manufactured in a third country will also be confirmed in a Q&A  [Source 1 Section 2.5ii] | X |  |  |  |
| Introduce new lines or new premises with limited prospective qualification [Source 1 Section 6.2i] |  | X |  |  |
| Perform concurrent process validation for medicines used in treatment of COVID19 patients [Source 1 Section 6.2ii] | X (clarification of an existing GMP provision) |  |  |  |
| Temporary changes to scheduled quality related tasks to free resources towards critical medicines used for treatments of patients infected with COVID19 [Source 1 Section 6.3 and 6.7] |  | X (deferral of some stability testing – in process of being added to UK flexibilities) |  | X (permitting use of flexibilities to all medicines, where necessary and proportionate) |
| Postponing / waiving testing in a third country [Source 1 Section 6.4i] | X |  |  |  |
| Postponing re-testing on importation into the EEA for medicines used in the treatment of COVID19 patients [Source 1 Section 6.4ii] |  |  |  | X (permitting use of flexibilities to all medicines, where necessary and proportionate. UK has wider criteria to permit the use of this flexibility, and is not mandating retrospective testing in the EEA) |
| Remote working of an RP [Source 1 Section 6.5i] | X (current UK practice) |  |  |  |
| Delegation of duties and responsibilities of an RP to another RP in the same group of companies [Source 1 Section 6.5ii] | X |  |  |  |
| Delegation of RP duties to a person who is not an RP [Source 1 Section 6.5iii] | X (current UK practice – named RP retains responsibility) |  |  |  |
| Replacement of RP at short notice [Source 1 Section 6.4iv] | X (expedited WDA(H) variations) |  |  |  |
| Use of new equipment / premises for storage and distribution with limited qualification [Source 1 Section 6.6] | X |  |  |  |
| Blood components for transfusion | | | | |
| N/A | N/A | N/A | N/A | N/A |
| Medical devices | | | | |
| Notified body audit easements  [Source 2] | X |  |  |  |
| Adoption of union wide derogations  [Source 6] | As within the transition period UK will need to align with this – we are seeking advice on the logistics of data sharing with the Commission. |  |  |  |
| Human plasma for fractionation | | | | |
| Distant assessment procedure and use of ‘statement of next inspection’ [Source 1 Section 2.3] | X |  |  |  |