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Guidance

Converting Centrally Authorised Products (CAPs) to UK Marketing Authorisations (MAs) from 1 January 2021, 'grandfathering' and managing lifecycle changes

This guidance covers ‘grandfathering’ and managing the lifecycle changes of medicinal products.

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From:
Medicines and Healthcare products Regulatory Agency
(https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)

New rules for January 2021

The UK has left the EU, and the transition period after Brexit comes to an end this year.

This page tells you what you'll need to do from 1 January 2021. It will be updated if anything changes.

For current information, read: Apply for a licence to market a medicine in the UK (https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk)

You can also read about the transition period (https://www.gov.uk/transition).

Contents

This guidance will apply from 1 January 2021 in line with the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019 (http://www.legislation.gov.uk/uksi/2019/775/contents/made). It is our intention to update these Regulations to reflect the change of implementation dates following the Transition Period.

From 1 January 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) will be the UK's stand-alone medicines and medical devices regulator, taking any decisions and carrying out any functions which were taken or carried out at EU-level except for decisions on Marketing Authorisation (MA) applications made through the European procedures to market products in Northern Ireland.

General approach to grandfathering of CAPs

All existing CAP MAs will automatically be converted into UK MAs effective in Great Britain (only) and issued with a UK MA number on 1 January 2021. These UK MAs are referred to in this guidance as "converted EU MAs". As a result of the implementation of the Northern Ireland Protocol, existing CAPs will remain valid for marketing products in Northern Ireland.

MAHs can choose to opt-out of the conversion process for all or some of their CAPs by notifying the MHRA in writing following which those UK MAs will be revoked. To opt out you must let the MHRA know by the end of 21 January 2021.

MAs for CAPs that are not currently marketed in the EU or UK can still be converted to Great Britain MAs. For the purposes of operating the Sunset Clause in accordance with regulation 67 Human Medicines Regulations 2012 (as amended), the period of three years during which the product has not been marketed in Great Britain will be restarted from the date of conversion to a Great Britain MA.

To facilitate the grandfathering process, the MHRA will issue one or more Product Licence (PL) numbers to CAPs based on the existing UK practice for determining how many separate national licences are needed across a product range. In most cases this means that fewer UK MA numbers will be needed in comparison with the number of European Commission authorisations because all pack sizes for a presentation will be covered by a single MA number.

The format of the UK MA valid only in Great Britain will be PLGB XXXXX/YYYY where XXXXX is the company number and YYYY is a sequential number for individual products. Where a CAP MAH already has a company number allocated by MHRA for existing national licences, that number will be used. If the CAP MAH does not have a company number allocated by MHRA then an application form for a number will be required.

There is no fee associated with the conversion from a CAP to a Great Britain MA.

If the MAH chooses to opt-out, their product(s) will no longer be licensed and must not be marketed in Great Britain. The MHRA will publish a list of products that have and have not been converted as a result of this exercise.

To support the ongoing regulation of these converted EU MAs, the MHRA needs essential baseline data to be submitted in the form of an initiating electronic Common Technical Document (eCTD) sequence together with certain other related MA-specific information for each converted EU MA.

MAHs will have a period of one year starting on 1 January 2021 to submit this data and related information in eCTD format. Until these initiating sequences are submitted and processed, it will not be possible to submit a variation for the converted EU MA unless there are exceptional circumstances relating to public health. There is no fee for the grandfathering process.

As with all national MAs, an annual service fee (https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees) will be due for converted EU MAs from 1 April 2021 unless the MAH opts out by the required date.

Actions that holders of converted EU MAs need to take

1. What to submit in the initiating sequence and other related information

Within the period of one year starting on 1 January 2021, the MAH must submit the following information to the MHRA for each converted EU MA. (This is the information which is specified in paragraph 9(3)(a) of new Schedule 33A to the Human Medicines Regulations 2012, as inserted by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019).

The data submission package must contain:

a) cover letter and declaration that only approved documentation is included in the initiating sequence. The cover letter should clearly identify the submission as a “CAP Grandfathering Submission” in the title.

b) a single eCTD initiating sequence for the converted EU MA representing the currently authorised and approved position. Where more than one dosage form or strength will be converted for the same product trade name, it is expected these will be handled as one eCTD dossier. If the product dossier refers to an Active Substance Master File, the MAH must ask the active substance supplier to submit that to MHRA if they have not already done so. We have published guidance on how to do this

c) a completed electronic application form (eAF) for each converted EU MA.

d) a summary list of all historical regulatory activity from the grant date of the original CAP until the data is submitted. This will include:

I. type of submission (such as initial new Marketing Authorisation Applications (MAA), Variation, Periodic Safety Update Report (PSUR), Renewal)

II. the date of submission to the European Medicines Agency (EMA) (optional if the outcome date is available)

III. summary of the submission (such as a short description of a variation)

IV. regulatory outcome (such as granted or not granted)

V. the date of the outcome

VI. eCTD sequence number of the submission (only for eCTD format submissions)

Alternatively, the historical document can mirror the format of the EU procedural steps document if this makes it easier to create.

e) notification of whether or not the product referred to in the converted EU MA is on the Great Britain market at the time the notification is given. If it is not, the MAH must tell us whether the product has been on the Great Britain market at any time after 1 January 2021 and, if so, the date it was withdrawn from the market (for the purposes of Article 23a and Article 24 (4-6) of Directive 2001/83EC – as implemented in regulations 67 and 73 of the Human Medicines Regulations 2012), the “Sunset Clause”). This information may be included in the cover letter. .

f) the Summary of Product Characteristics (SmPC) currently approved by corresponding EU procedure both in pdf format and in the Summary approach to variations (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/914112/Summary_approach_to_variations.pdf) (PDF, 41.5KB, 1 page).

g) the packaging labels and leaflets as currently approved by the corresponding EU procedure which are:

I. the outer packaging of the medicinal product;

II. the immediate packaging of the medicinal product; and

III. the package leaflet for the medicinal product.

2. Further advice on documentation

The summary of historical regulatory activity (section d above) must be included in the Working Documents folder of the eCTD and the notification of marketing status (section e above) must be included in the cover letter.

The cover letter, electronic Application Form (eAF) and currently approved SmPC, Packaging and Patient Information Leaflet (PIL) must be included in the appropriate folders in Module 1 of the eCTD sequence.

The submission must reflect only what is relevant to the product intended for Great Britain so that this can be used as the start of the lifecycle for the nationally registered product(s). Inclusion of non-UK specific information could, over time, lead to inaccurate information held within the database and may lead to difficulties with the technical validation of subsequent submissions.

The eCTD sequence must pass technical validation (sections 4 and 5 below). The MHRA will apply an abbreviated content validation and will not issue a validation report, the presence of a SmPC, PIL and packing information are mandatory.

The MHRA expects that all information representing the currently authorised and approved position that has previously been submitted in eCTD format will be included in the initiating sequence submission. However, it is acknowledged that some information may not be available in electronic format, particularly for older products, and that it may not be possible for the initiating sequence to be entirely complete.

In these circumstances, the MAH should submit what is available and the MHRA will accept a partially completed sequence, provided:

- The MAH makes all reasonable endeavours to include any information available in an electronic format other than eCTD format, in the appropriate eCTD structure in accordance with eCTD technical validation criteria. Avoid placing documents in the Working Documents section of the

eCTD structure and use it by exception only.

The holder of the converted EU MA responds to a request to provide any information related to the MA either before or after submission of the initiating sequence, including historical information, within the time period specified in the request.

3. How to submit the application

Except for applications made through European procedures to market in Northern Ireland, the MHRA does not expect to be able to receive submissions through the Common European Submission Portal (CESP). We have developed a new national portal to be ready by 1 January 2021 and expect that submissions will be made via this portal. Information on the use of this portal will be published in advance of 1 January 2021.

4. Specific advice on preparing the initiating sequence

Background information on the latest version of the eCTD standard, including EU guidance on Module 1 information and the electronic application form can be found on the EMA e-submissions website (http://esubmission.ema.europa.eu/ectd/).

The date on which the minimal or full initiating sequence is received is referred to as “the data submission date”. The MAH should construct a single, technically valid, eCTD sequence (the “Converted EU MA Initiating Sequence”) showing the current, approved information (“current authorised view”) of the converted EU MA(s) on the data submission date.

Information that has been “replaced” or “deleted” during the life cycle of the CAP MA that the converted EU MA is derived from should not be included.

The sequence should be assigned as sequence number 0000, submission type “maa” and submission unit assigned as “initial”.

Points to consider:

a) Only include Great Britain relevant information. Remove previous cover letters and application forms, and remove all product information except Great Britain specific information.

b) Remove all PSUR information. PSURs will not need to be submitted in the eCTD lifecycle.

c) Historical EU information about the PV Master File, etc. in module 1.8. is not required. New information must be submitted as a later type IA variation.

d) Remove all responses to questions in module 1 - i.e. remove any discussion and only show the outcome in terms of the documents in the rest of modules 1-5.

e) The submission must include a full eAF) for each of the products in the application. The “Initial MAA” eAF should be used with the initiating sequence and only approved information should be included - any changes to the approved information must be submitted as a variation after the submission of the initiating sequence using the normal process for variations to national MAs (see information on variations in sections 6 - 8).

f) The summary of historical regulatory activity must begin with the original CAP MAA submission and continue up to the data submission date. This must be a list of the submission events in a table format, not the individual eCTD sequences that were submitted for each event (noting that for some products these events will predate the eCTD). Please submit this in the same format as the tracking table in module 1.0.

g) The initiating sequence must be a valid eCTD submission, built to EU module 1 v3.0.2 and ICH v3.2.2 standards or, if these are superseded, by such standards that are applicable at the time of submission. Non-functioning hyperlinks are acceptable if they are unavoidable.

h) The initiating sequence should include multiple dosage forms and strengths in a single eCTD dossier lifecycle.

5. Submitting the initiating sequence in two steps

The MHRA strongly prefers MAHs submit the initiating sequence as a single event. However, it is recognised that some MAHs may need to submit variations, renewals or Article 61(3) notifications to the MA before they can produce the complete initiating sequence.

In these circumstances, the MAH can use a two-step process by first submitting a minimal initiating sequence containing at least the mandatory documents at an early point following 1 January 2021.

The mandatory documents are:

- those described in section 1f) and 1g)
- an eAF containing at least the mandatory information (as defined in the eAF section 1c))
- a cover letter and declaration (see section 1a)).
- a statement in the cover letter that this is a minimal initiating sequence and commitment to send the complete initiating sequence within a period of one year starting on 1 January 2021.

The sequence must also be technically valid (see section 4g) above).

If MAHs take this approach, a further complete initiating sequence, containing all documents electronically and the specific other related information defined in section 2, must still be submitted within a period of one year starting on 1 January 2021. The sequence number of this submission should be sequential to the earlier minimal initiating sequence and any subsequent variations or other submissions.

If MAHs submit an early minimal initiating sequence we advise making every effort to include Module 3 (quality) documents. This module is frequently varied and, if the documents are not available, any subsequent variation to M3 is likely to be delayed by the need to request missing data.

6. General approach to variations to converted EU MAs from 1 January 2021

In general, the MHRA will not consider variations to converted EU MAs before at least a minimal initiating sequence (as defined in section 5) and related documentation (the “data submission package”) have been submitted. The date on which the minimal or full initiating sequence is received is referred to as the data submission date.

In exceptional circumstances, we may consider a variation before the data submission date if, in our view, the following circumstances apply:

- the variation is necessary on urgent safety grounds
- the variation is necessary in order to maintain supplies of a particular medicinal product to patients in Great Britain
- there are other necessary or beneficial reasons for considering the variation in advance of receipt of the baseline information

If the holder of a converted EU MA considers that these conditions may apply, they should contact the agency's Regulatory Information Service (https://www.gov.uk/guidance/contact-mhra#regulatory-information-service-ris) to ask for agreement from MHRA and discuss how to proceed.

Variation applications may be included with the data submission package as separate eCTD sequences in line with the normal national MA variation process. However the variation will only be considered after the baseline is processed and will be treated as if it was submitted after the data submission date.

The table at the bottom of this page provides a summary of the approach to variations that MHRA will take in the different scenarios which may arise.

7. Approach to variations submitted to the EMA but not granted before 1 January 2021

To simplify handling of variation submissions the MHRA has adopted a pragmatic approach to these submissions.

Type IA Variations

For minor variations of Type IA and Type 1B, these may be implemented in relation to the converted EU MA at the same time as they are implemented in relation to the corresponding EU MA. The variation must be included in the initiating sequence submission as if it had already been accepted in Great Britain.

The MAH must inform the MHRA when submitting the sequence if the variation was rejected or refused by the EMA after 1 January 2021 but before the data submission date, and the variation must be removed from the initiating sequence.

The variations will be deemed to be accepted unless the holder of the converted EU MA is notified, within 30 days of the data submission date, that it has been rejected.

The details of the variations must be included in the summary of historical regulatory activity submitted with the initiating sequence

Type II Variations

For major variations of type II, if the variation had reached positive Committee for Medicinal products for Human Use (CHMP) opinion stage before 1 January 2021:

- the variation must be included within the initiating sequence submission as if it had already been accepted in Great Britain
- the variation may be implemented in relation to the converted EU MA at the same time as it is implemented in relation to the corresponding EU MA
- the details of the type II variation must be included in the summary of historical regulatory activity submitted with the initiating sequence
- no fee will apply for these variations
- the MHRA will notify the holder of the converted EU marketing authorisation within 30 days beginning with the data submission date if the variation is rejected, in which case the holder must cease to apply the rejected variation immediately after receipt of the notification.

If the Type II variation had not reached CHMP opinion and at 1 January 2021 was in clock-stop following a request for further information:

- a copy of the variation application must be included in the data submission package as a separate eCTD sequence (sequence 0001 and so on)
- the variation will only be considered after the initiating sequence is processed.
- no fee will apply for these variations. Great Britain will review responses when submitted.

If the Type II variation had not reached CHMP opinion and at 1 January 2021 was before clock-stop:

- a copy of the variation application must be included in the data submission package as a separate eCTD sequence (sequence 0001 and so on).
- the variation will only be considered after the initiating sequence is processed.
- the appropriate fee will apply (https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees) for these variations and the variation will be reviewed by MHRA.

8. Approach to variations to converted EU MAs applied for from 1 January 2021

This advice applies where the holder of a converted EU MA has notified the EMA of, or applied to the EMA for, a variation of the EU MA from 1 January 2021 but before the data submission date and intends the variation to be made in relation to the converted EU MA.

Type IA Variations

For minor variations of Type IA these may be implemented in relation to the converted EU MA at the same time as they are implemented in relation to the corresponding EU MA. The variation must be included in the initiating sequence submission as if it had already been accepted in Great Britain.

The MAH must inform the MHRA when submitting the sequence if the variation was rejected by the EMA from 1 January 2021 but before the data submission date, and the variation must be removed from the initiating sequence.

The variation will be deemed to be accepted unless the holder of the converted EU MA is notified, within 30 days of the data submission date, that it has been rejected.

The details of the variation must be included in the summary of historical regulatory activity submitted with the initiating sequence.

Type IB and Type II Variations

For minor variations of type IB, and major variations of type II, if the variation has not been rejected by the EMA before the data submission date, a copy of the variation application must be included in the data submission package as a separate eCTD sequence (sequence 0001 and so on). The variation will only be considered after the baseline is processed.

Type IB/II variations will be reviewed by MHRA and the appropriate fee will apply (https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees).

The table at the bottom of this page provides a summary of the approach to variations that MHRA will take in the different scenarios which may arise.

9. General approach to renewals to converted EU MAs from 1 January 2021

For the purpose of renewals, converted EU MAs are treated as if they were granted on the date on which the corresponding EU MA was granted. The converted EU MA will therefore have the same renewal date in the UK as in the EU. In general, the MHRA will not consider renewals to converted EU MAs before at least a minimal initiating sequence (as defined in section 5) and related documentation (the “data submission package”) has been received. The date on which the minimal or full initiating sequence is received is referred to as “the data submission date”.

In exceptional circumstances, we may consider a renewal (for either a converted EU MA or converted conditional EU MA) before the data submission date (in the absence of a minimal or fully initiating sequence) where:

- the renewal is necessary on urgent safety grounds
- the renewal is necessary in order to maintain supplies of a particular medicinal product to patients in Great Britain
- there are other necessary or beneficial reasons for considering the renewal in advance of receipt of the baseline information

If the holder of a converted EU MA considers that these conditions may apply, they should contact the agency’s Regulatory Information Service (https://www.gov.uk/guidance/contact-mhra#regulatory-information-service-ris) to ask for agreement from MHRA and to discuss how to proceed.

Renewal applications may be included with the data submission package as separate eCTD sequences in line with the normal national MA renewal process, but will only be considered after the baseline is processed.

After the data submission date, the normal renewal application process for national MAs and fees will apply.

10. Approach to Renewals submitted to the EMA but not granted before 1 January 2021

Converted EU MAs

This section applies where the holder of a converted EU MA has made an application to the EMA for a renewal of the EU MA before 1 January 2021 but no final decision was made by the EMA before 1 January 2021.

A copy of the renewal application must be included in the data submission package as a separate eCTD sequence (sequence 0001 and so on). The renewal will only be considered after the baseline is processed

In considering the application:

Where before 1 January 2021, the CHMP has given a positive final opinion and the UK concurred, the renewal will be treated as accepted:

- the renewal must be included within the initiating sequence submission as if it had already been accepted in Great Britain
- the details of the renewal must be included in the summary of historical regulatory activity submitted with the initiating sequence
- no fee will apply for these renewals

If, before 1 January 2021, the renewal had not reached CHMP opinion and was in clock-stop following a request for further information:

- a copy of the renewal application must be included in the data submission package as a separate eCTD sequence (sequence 0001 and so on)
- the renewal will only be considered after the initiating sequence is processed
- no fee will apply for these renewals

If before 1 January 2021 the renewal had not reached CHMP opinion and was before clock stop:

- a copy of the renewal application must be included in the data submission package as a separate eCTD sequence (sequence 0001 and so on).
- the renewal will only be considered after the initiating sequence is processed.
- the appropriate fee will apply (https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees) for these renewals and the renewal will be reviewed by the MHRA.

Where, before 1 January 2021, the CHMP had given a negative final opinion or had given a positive final opinion but the UK had recorded a divergent opinion, the renewal will be considered in line with normal MHRA practice:

- a copy of the renewal application must be included in the data submission package as a separate eCTD sequence (sequence 0001 and so on).
- the renewal will only be considered after the initiating sequence is processed.
- the appropriate fee will apply (https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees) for these renewals

Converted conditional EU MAs

This section applies where the holder of a converted EU MA which was granted as a conditional MA has made an application to the EMA for a Renewal of the EU MA before 1 January 2021 but no final decision has been made by the EMA before 1 January 2021.

A copy of the renewal application must be included in the data submission package as a separate eCTD sequence (sequence 0001 and so on). The renewal will only be considered after the baseline is processed.

In considering the application:

- where, before 1 January 2021, the CHMP had given a positive final opinion and the UK concurred, the renewal will be treated as accepted
- where, before 1 January 2021, the CHMP had not given an opinion or had given a negative final opinion or had given a positive final opinion but the UK recorded a divergent opinion, the renewal will be reviewed by the MHRA

11. Approach to applications for renewals made from 1 January 2021

Converted EU MAs

This section applies where the holder of a converted EU MA is due to make an application for a Renewal of a converted EU MA during the period of one year following 1 January 2021.

Where this applies, the MAH must submit an application for renewal in accordance with the usual time limits. The application should be submitted as a separate eCTD sequence (sequence 0001 and so on) along with the initiating sequence (minimal or complete) if this has not already been submitted. The renewal will only be considered after the baseline is processed.

The MHRA will consider the application, which should be accompanied by the appropriate fee.

The MA will remain in force until the MHRA notifies the MAH of its decision on the renewal application.

Converted conditional EU MAs

This section applies where the holder of a converted EU MA that was granted as a conditional MA is due to make an application for a Renewal of the MA during the period of one year following 1 January 2021 and ending on the data submission date.

Where this applies, the MAH must submit an application for renewal in accordance with the usual time limits, and the application should be submitted as a separate eCTD sequence (sequence 0001 and so on) along with the initiating sequence (minimal or complete) if this has not already been submitted. The renewal will only be considered after the baseline is processed.

The MHRA will consider the application in accordance with new regulation 66B. No fee is due.

The MA will remain in force until the MHRA notifies the MAH of its decision on the renewal application.

12. General approach to Article 61(3) notifications for converted EU MAs from 1 January 2021

In general, the MHRA will not consider Article 61(3) notifications for converted EU MAs before at least a minimal initiating sequence (as defined in section 5) and related documentation (the “data submission package”) has been received. In exceptional circumstances we may consider an Article 61(3) notification before the data submission date and in the absence of a minimal or full initiating sequence, if we are of the view that:

- the notification is necessary on urgent safety grounds
- the notification is necessary in order to maintain supplies of a particular medicinal product to patients in Great Britain or
- there are other necessary or beneficial reasons for considering the variation in advance of receipt of the baseline information.

If the holder of a converted EU MA considers that these conditions may apply, they should contact the agency’s Customer Service Centre (https://www.gov.uk/guidance/contact-mhra#customer-services) to ask for agreement from MHRA and discuss how to proceed.

Article 61(3) notifications may be included with the data submission package as separate eCTD sequences in line with the normal national MA notification process but will only be considered after the baseline is processed.

After the data submission date, the normal Article 61(3) process for national MAs and fees will apply.

13. Approach to Article 61(3) notifications submitted to the EMA but not granted before 1 January 2021

Where:

- the holder of a converted EU MA has made an Article 61(3) notification for the corresponding EU MA before 1 January 2021,
- the change is applicable to the product information intended for the UK market,
- the 90-day period referred to in Article 61(3) has not elapsed,
- the EMA has not objected to the change,

the notification must be included within the initiating sequence submission as if it had already been accepted in Great Britain. The change may be put in effect at the same time as for the EU MA.

No fee will apply for these notifications.

The notification will be deemed to be accepted unless the holder of the converted EU MA is notified that it has been rejected within 30 days of the data submission date.

The details of the Article 61(3) notification must be included in the summary of historical regulatory activity submitted with the initiating sequence and the MAH must notify the MHRA if the EMA rejects the notification from 1 January 2021 but before the data submission date.

14. Approach to Article 61(3) notifications made from 1 January 2021

Where the holder of a converted EU MA has made an Article 61(3) notification for the EU MA from 1 January 2021 but before the data submission date, and the change is applicable to the product information intended for the Great Britain market, the notification must be included within the initiating sequence submission as if it had already been accepted in Great Britain. The change may be put in effect at the same time as for the EU MA.

No fee will apply for these notifications.

The notification will be deemed to be accepted unless the holder of the converted EU MA is notified that it has been rejected within 30 days of the data submission date.

15. Legal presence requirement

For grandfathered CAP MAs with a non-UK MAH, there is a requirement to establish an MAH in the UK within 24 months of 1 January 2021 (by 1 January 2023). MAHs have two options:

1. Submit a Change of Ownership application (COA) after the submission of the baseline initiating sequence within 21 months after the transition period
2. Include the COA in the initiating sequence as if it had already been approved by the MHRA and state in the cover letter that this option had been adopted.

MAHs using option 2 must ask for PL numbers to be issued for the UK MAH by requesting them from capconversion@mhra.gov.uk and use them in the eAF and the initiating sequence. The initiating sequence must contain the current granted EU patient information and, additionally, mock-ups of the UK patient information should be included or text-only versions.

If text-only versions are provided, the MAH will need to submit a subsequent variation to approve mock-ups of the UK patient information within 2 years from 1 January 2021 (by 1 January 2023).

The MHRA would prefer that MAHs took the latter approach and included the change in the initiating sequence. There will be no fee in either case.

For MAHs who choose to submit a COA should see our information on change of ownership published on our website (https://www.gov.uk/guidance/medicines-marketing-authorisation-transfer-ownership).

Summary of approach to variations

Summary approach to variations (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/914112/Summary_approach_to_variations.pdf) (PDF, 41.5KB, 1 page)

Variation	Positive CHMP Opinion Stage before exit day	MHRA assessment	Fee payable	Include in Initiating Sequence
Type IA: (i) Submitted to EMA before 1 January 2021 and not rejected or, (ii) submitted to EMA on or after 1 January 2021 and not rejected before data submission date	N/A	No	No	Yes, (and list in summary of historical regulatory activity accompanying Initiating Sequence)
Type IB: Submitted to EMA but not granted before 1 January 2021	Yes	No	No	Yes, (and list in summary of historical regulatory activity accompanying Initiating Sequence)
Type IB: Submitted to EMA but not granted before 1 January 2021	No	No	No	Yes, (and list in summary of historical regulatory activity accompanying Initiating Sequence)

Variation	Positive CHMP Opinion Stage before exit day	MHRA assessment	Fee payable	Include in Initiating Sequence
Type II: Submitted to EMA but not granted before 1 January 2021	Yes	No	No	Yes, (and list in summary of historical regulatory activity accompanying Initiating Sequence)
Type II in clock stop: Submitted to EMA but not granted before 1 January 2021, And in clock stop	No	Yes, assessment of replies	No	No: Separate Submission needed along with or after Initiating Sequence (either minimal or complete)
Type II in clock stop: Submitted to EMA but not granted before 1 January 2021, And before procedure first clock stop	No	Yes	Yes	No: Separate Submission needed along with or after Initiating Sequence (either minimal or complete)
Type IB/II variations: Submitted to EMA on or after 1 January 2021	N/A	Yes	Yes	No: Separate Submission needed along with or after Initiating Sequence (either minimal or complete)

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Transition period

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- MHRA post-transition period information (https://www.gov.uk/government/collections/mhra-post-transition-period-information)

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- Marketing authorisations, variations and licensing guidance (https://www.gov.uk/topic/medicines-medical-devices-blood/marketing-authorisations-variations-licensing)