EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Guidance for applicants for the preparation of the 'precise scope' section of the variation application form

Introduction

This guidance aims at supporting applicants in completing the 'Precise scope and Background for a change, and Justification for grouping, worksharing and classification for unforeseen changes (if applicable)' (hereinafter called the 'Precise scope') section of the Application Form for Type I and Type II variations.

It provides guidance on the information to be included in this section and some examples of changes applied for each of the scopes listed in the Guidelines on the details of the various categories of variation, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use, and on the documentation to be submitted pursuant to those procedures (hereinafter called 'the Variations Guidelines').

It also aims at improving the description clarity of the exact change(s) applied for and, ultimately, to facilitate the EMA validation and review process of the applications.

This guidance is not mandatory, it is rather meant as support for the preparation of applications for variations in addition to the EMA/CMDh explanatory notes on variation application form, the CMDh Q/A-List for the submission of variations according to Commission Regulation (EC) 1234/2008, the EMA practical guidance on application form for centralised Type IA and Type IB variations and the published pre-notification checklists for Type IAs, Type IBs, Type II quality variations and Type II (non) clinical variations.

Content of the section

As detailed in EudraLex Volume 2B - Presentation and content of the dossier, the 'Application for Variation to a Marketing Authorisation' Form includes a free text section to detail the 'Precise Scope'.

This section should include a brief explanation of the change(s) applied for. When the change(s) is/are submitted as a consequence of a previous regulatory procedure (e.g. recommendation), a reference should be provided. The precise scope aims at providing a complete and concise description of the change(s) applied for. Some examples of wordings that could be used are detailed in the Annex of this guidance.

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For grouped applications (more than one scope), applicants are encouraged to add the classification indent from the Variations Guidelines to the description of each change applied for, e.g.:

Type IA (Q.II.b.3.a)- {description of the change}
Type II (Q.II.b.3.b)- {description of the change}
Type IB (Q.II.b.5.a)- {description of the change}

When additional changes not requiring a variation (i.e. editorial changes) are proposed within a variation, these should also be reflected in the precise scope. The following wording may be used:

'In addition, the applicant has taken the opportunity to <update> <amend> <sections of the CTD module(s)>'.

For quality variations affecting the Risk Management Plan (RMP). The following wording should be added to the precise scope describing the quality changes:

<An updated RMP version {#} has also been submitted>.

With regards to 'editorial changes', the applicant is strongly encouraged to consult the published guidance on 'Classification of changes: questions and answers' prior to submitting the variation application. The EMA will reserve the right to reject editorial changes considered too extensive for the type of procedure used for their inclusion or that would require to be addressed via a separate variation.

For variations affecting the Annexes, if the applicant takes the opportunity to bring them in line with the latest QRD template and/or to make updates to list of local representatives and/or implement minor editorial changes in the PI, this should be reflected in the precise scope. The following wording may be used:

'In addition, the applicant has taken the opportunity to <update the list of local representatives in the PL> <and> <implement minor editorial changes in <section<s> X, X and X of the SmPC> <Annex II> <Labelling> <and> <PL>.'

'Furthermore, the PI has been brought in line with the latest QRD template (version xx).'

For acceptability of editorial changes within a variation application for centrally approved products please refer to the EMA post-authorisation procedural advice for users of the centralised procedure

- For groupings of variations, a justification for its acceptability should be provided including, as appropriate, e.g. either the relevant reference in Annex III of the Commission Regulation (EC) No 1234/2008, reference to examples published by CMD or the Agency, or to the pre-submission agreement with the Agency on the proposed grouping.
- For worksharing procedures, the justification should refer to the pre-submission contacts with the Agency.
- For default Type IB variations i.e. 'z'- category (except Type IB variations classified as 'z'- category following a CMDh Art.5 recommendation), a justification for the proposed classification has to be given. Applicants are reminded that, in accordance with Q.3.1 of the published CMDh Q/A-List for the submission of variations according to Commission Regulation (EC) 1234/2008, if a change is not mentioned in Annex II of the Variation Regulation (EC) 1234/2008 or in the classification guideline ('.z' scopes), this change can be submitted as a Type IB variation by default. However, if the change in the view of the applicant has a significant impact on quality, safety and efficacy of the product, a Type II variation has to be submitted. Such scopes can only be classified as Type IA/IA_{IN} changes if such recommendation has been agreed via an Art. 5 procedure and, consequently,

included in the CMDh Recommendation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) 1234/2008

ANNEX

EXAMPLES OF 'PRECISE SCOPE' SECTION WORDING FOR EACH CATEGORY OF THE VARATION CLASSIFICATION GUIDELINE

EXAMPLES OF 'PRECISE SCOPE' SECTION WORDING FOR EACH CATEGORY OF THE VARATION CLASSIFICATION GUIDELINE

The list below provides some examples of wordings and details that may be considered by applicants for each of the categories of the variation classification guideline.

ADMINISTRATIVE CHANGES

E.1.a, E.1.b

To change the (invented) name of the finished product from {old name} to {new name}.

E.2

To change the name of the <active substance><excipient><medical device (part)><packaging component> from {old name} to {new name}.

E.3

To include the ATC Code {(code)} in Section 5.1 of the Summary of Product Characteristics (SmPC).

To change the ATC Code of {active substance} from {current ATC Code} to {new ATC Code}.

E.4.a

To change the <name> <and> <address> of the <marketing authorisation> <scientific opinion> holder from {current name and/or full address} to {new name and/or full address}. <The address remains unchanged.> It is hereby confirmed that the legal entity remains unchanged.

E.4.b

To change the name of the site responsible for <<{activity/ies}> <supplying> <manufacturing> <storage> <primary packaging> <secondary packaging> <quality control testing> <and> <batch release>> of <<{substance or component}> <the active substance {active substance}> <starting material> <reagent> <intermediate {intermediate}> <excipient {excipient}> <<master cell bank> <and> <working cell bank>> <the finished product {finished product}> <packaging component> <medical device (part)>> from {current name} {full address} to {new name}. The address remains unchanged.

To update the address of the site responsible for <<{activity/ies}> <supplying> <manufacturing> <storage> <primary packaging> <secondary packaging> <quality control testing> <and> <batch release>> of <<{substance or component}> <the active substance {active substance}> <starting material> <reagent> <intermediate {intermediate}> <excipient {excipient}> <<master cell bank> <and> <working cell bank>> <the finished product {finished product}> <packaging component> <medical device (part)>> from {current name} {full address} to {new full address}. There is no change in the location of the site.

To change the <name> <and> <address> of the <ASMF Holder> of the active substance {active substance}, ASMF {EMEA or EU ASMF number} from {current name} {full address} to <{new name}> <{new name}> <{new full address}>. <The address remains unchanged.>

E.4.c

To change the name of the site responsible for <<{activity/ies} of> <supplying> <manufacturing> <importer> <storage> <primary packaging> <secondary packaging> <quality control testing> <and> <batch release>> of <<{substance or component}> <the active substance {active substance}> <starting material> <reagent> <intermediate {intermediate}> <excipient {excipient}> <<master cell bank> <and> <working cell bank>> <the finished product {finished product}> <packaging component> <medical device (part)>> from {current name} {full address} to {new name}. The address remains unchanged.

To update the address of the site responsible for <<{activity/ies} of> <supplying> <manufacturing> <importer> <storage> <primary packaging> <secondary packaging> <quality control testing> <and> <batch release>> of <<{substance or component}> <the active substance {active substance}> <starting material> <reagent> <intermediate {intermediate}> <excipient {excipient}> <<master cell bank> <and> <working cell bank>> <the finished product {finished product}> <packaging component> <medical device (part)>> from {current name} {full address} to {new full address}. There is no change in the location of the site.

To change the <name> <and> <address> of the <ASMF Holder> of the active substance {active substance}, ASMF {EMEA or EU ASMF number} from {current name} {full address} to <{new name}> <{new name}> <{new full address}>. <The address remains unchanged> <There is no change in the location of the site>.

E.5

To delete the ASMF Holder {name and full address}, ASMF {EMEA or EU ASMF number}.

To delete {name and full address} as a site responsible for <<{activity/ies} of> <supplying> <manufacturing> <importer> <storage> <primary packaging> <secondary packaging> <quality control testing> <and> <batch release>> of <<{substance or component}> <the active substance {active substance}> <starting material> <reagent> <intermediate {intermediate}> <excipient {excipient}> <<master cell bank> <and> <working cell bank>> <the finished product {finished product}> <packaging component> <medical device (part)>>.

To delete the following manufacturing sites:

- {name and full address} as a site responsible for <<{activity/ies} of> <supplying> <manufacturing> <importer> <storage> <primary packaging> <secondary packaging> <quality control testing> <and> <batch release>> of <<{substance or component}> <the active substance {active substance}> <starting material> <reagent> <intermediate {intermediate}> <excipient {excipient}> <<master cell bank> <and> <working cell bank>> <the finished product {finished product}> <packaging component> <medical device (part)>>.
- {name and full address} as a site responsible for <<{activity/ies} of> <supplying> <manufacturing> <importer> <storage> <primary packaging> <secondary packaging> <quality control testing> <and> <batch release>> of <<{substance or component}> <the active substance {active substance}> <starting material> <reagent> <intermediate {intermediate}> <excipient

{excipient}> <<master cell bank> <and> <working cell bank>> <the finished product {finished product}> <packaging component> <medical device (part)>>.

QUALITY CHANGE: ACTIVE SUBSTANCE

Q.I.a.1.a

To add {name and full address} as an alternative site responsible for {activity/ies} of the <active substance {active substance}> <intermediate {substance} used in the manufacturing process of the active substance {active substance}>.

To replace {name and full address} with {name and full address} as site responsible for {activity/ies} of the <active substance {active substance}> <intermediate {substance} used in the manufacturing process of the active substance {active substance}>.

Q.I.a.1.b

To add {name and full address} as an alternative site responsible for <<{activity/ies} of the <active substance {active substance}> <<intermediate {substance} used in the manufacturing process of the active substance {active substance}> using <a substantially different route of synthesis> <substantially different manufacturing conditions>.

To replace {name and full address} with {name and full address} as a site responsible for <<{activity/ies} of the <active substance {active substance}> <<intermediate {substance} used in the manufacturing process of the active substance {active substance}> using <a substantially different route of synthesis> <substantially different manufacturing conditions>.

Q.I.a.1.c

To add {name and full address} as an alternative site responsible for <starting material> <reagent> {substance} used in the manufacturing process of the active substance {active substance}>.

To replace {name and full address} with {name and full address} as a site responsible for <starting material> <reagent> {substance} used in the manufacturing process of the active substance {active substance}>.

Q.I.a.1.d

To add {name and full address} as an alternative site responsible for the manufacturing of the <biological> <active substance {active substance}> <<intermediate> <starting material> <reagent> <raw material> {substance} used in the manufacturing process of the active substance {active substance}>.

To replace {name and full address} with {name and full address} as a site responsible for the manufacturing of the <biological> <active substance {active substance}> <<intermediate> <starting material> <reagent> <raw material> {substance} used in the manufacturing process of the active substance {active substance}> <which may have a significant impact on the quality, safety or efficacy of the finished product> <for which an assessment of viral safety and/or TSE risk is required>.

Q.I.a.1.e

To add {name and full address} as an alternative <herbal starting material supplier> <herbal active substance manufacturing site> of {active substance}.

To replace {name and full address} with {name and full address} as a <herbal starting material supplier> <herbal active substance manufacturing site> of {active substance}.

Q.I.a.1.f

To add {name and full address} as a site responsible for {activity/ies} of the active substance {active substance} supported by an ASMF {EMEA or EU ASMF number}.

Q.I.a.1.g

To add {name and full address} as an alternative site responsible for sterilisation (using a Ph.Eur. method) of the active substance {active substance}.

To replace {name and full address} with {name and full address} as a site responsible for sterilisation (using a Ph.Eur. method) of the active substance {active substance}.

Q.I.a.1.h

To add {name and full address} as an alternative site responsible for micronisation of the active substance {active substance}.

To replace {name and full address} with {name and full address} as a site responsible for micronisation of the active substance {active substance}.

Q.I.a.1.i

To add {name and full address} as an alternative site responsible for batch control/testing of the <active substance {active substance}> <<starting material {substance}> <intermediate {substance} used in the manufacture of the active substance {active substance}> applying a <biological> <immunological> <immunochemical> method.

To replace {name and full address} with {name and full address} as a site responsible for batch control/testing of the <active substance {active substance}> <<starting material {substance}> <intermediate {substance} used in the manufacture of the active substance {active substance}> applying a <biological> <immunological> <immunochemical> method.

Q.I.a.1.j

To add {name and full address} as an alternative site responsible for batch control/testing of the <active substance {active substance}> <<intermediate> <starting material> {substance} used in the manufacturing process of the active substance {active substance}>.

To replace {name and full address} with {name and full address} as a site responsible for batch control/testing of the <active substance {active substance}> <<intermediate > <starting material> {substance} used in the manufacturing process of the active substance {active substance}>.

Q.I.a.1.k

To add {name and full address} as an alternative site responsible for storage of the <Master Cell Bank> <and> <Working Cell Banks>.

To replace {name and full address} with {name and full address} as a site responsible for storage of the <Master Cell Bank> <and> <Working Cell Banks>.

Q.I.a.2.a

Minor change in the manufacturing process of the <active substance {active substance}> <<intermediate> <starting material> {substance} used in the manufacture of the active substance {active substance}> to {brief description of the change}.

Q.I.a.2.b

Major change to the manufacturing process of the <active substance {active substance}> <<intermediate > <starting material> {substance} used in the manufacturing process of the active substance {active substance}> to {brief description of the change}.

Q.I.a.2.c

Change in the <geographical source> <and> <manufacturing process> of the herbal substance {substance} to {brief description of the change}.

Q.I.a.2.d

Minor change to the restricted part of the {name of holder} ASMF {EMEA or EU ASMF number} to {brief description of the change}.

Q.I.a.2.e

Minor change in the manufacturing process of the <active substance {active substance}> to delete one of the manufacturing processes.

Q.I.a.3.a

To increase the batch size <range> of the <active substance {active substance}> <intermediate {intermediate} used in the manufacturing process of the active substance> <manufactured at {name of site, if the change is site-specific}> from {approved batch size} to {proposed batch size}.

To include an alternative batch size of {proposed batch size} for the <active substance {active substance}> <intermediate {intermediate} used in the manufacturing process of the active substance {active substance}> <manufactured at {name of site, if the change is site-specific}> in addition to the currently approved batch size(s) of {currently approved size(s)}.

Q.I.a.3.b

To decrease the batch size <range> of the <active substance {active substance}> <intermediate {intermediate} used in the manufacturing process of the active substance {active substance}>

<manufactured at {name of site, if the change is site-specific}> from {approved batch size} to {proposed batch size}.

Q.I.a.3.c

To <increase> <decrease> the batch size <range> of the <biological active substance {active substance}> <intermediate {substance} used in the manufacture of the active substance {active substance}> <manufactured at {name of site, if the change is site-specific}> from {approved batch size} to {proposed batch size}.

Q.I.a.3.d

To <increase> <decrease> the scale of the <biological active substance {active substance}> <manufactured at {name of site, if the change is site-specific}> from {approved batch size} to {proposed batch size} without process change.

Q.I.a.4.a

Minor change of the in-process control limits for {test} applied during the manufacture of the <active substance {active substance}> <<intermediate > <starting material> {substance} used in the manufacturing process of the active substance {active substance}> from {current value} to {proposed value}.

Q.I.a.4.b

To add {test} as a <new> <an alternative> in-process control limits applied during the manufacture of the <active substance {active substance}> <<intermediate > <starting material> {substance} used in the manufacturing process of the active substance {active substance}>. <The limit is set to {limit}>.

Q.I.a.4.c

To delete the <non-significant> <obsolete> in-process control limits {test} applied during the manufacture of the <active substance {active substance}> <<intermediate > <starting material> {substance} used in the manufacturing process of the active substance {active substance}>.

Q.I.a.4.d

To widen the in-process control limits for {test}, applied during the manufacture of the <active substance {active substance}> <<intermediate > <starting material> {substance} used in the manufacturing process of the active substance {active substance}>, from {current value} to {proposed value}.

Q.I.a.4.e

To delete the {test} in-process test applied during the manufacture of the <active substance {active substance}> <<intermediate > <starting material> {substance} used in the manufacturing process of the active substance {active substance}>.

Q.I.a.4.f

To change to the {procedure} analytical procedure for the {test} in-process control to {brief description of the change}.

Q.I.a.4.g

To replace the {test} in-process control applied during the manufacture of the <active substance {active substance}> <<intermediate > <starting material> {substance} used in the manufacturing process of the active substance {active substance}> with {alternative test}.

Q.I.a.5.a

Seasonal update of the composition of the vaccine strains officially recommended by WHO and CHMP for the season {proposed season}, which are the following: {proposed strains}.

Q.I.a.6.a

To add <serotype {proposed serotype}> <strain {proposed strains}> <antigen {proposed antigen}> <coding sequence {proposed coding sequence}> for <human coronavirus> vaccine {vaccine}.

To replace {current serotype, strains, antigen, coding sequence} with {proposed serotype, strains, antigen, coding sequence} for <human coronavirus> vaccine {vaccine}.

Q.I.a.6.b

To delete <serotype {serotype}> <strain {strains}> <antigen {antigen}> <coding sequence {coding sequence}> for <human coronavirus> vaccine {vaccine}.

Q.I.b.1.a

To change the {attribute} specification acceptance criteria of the finished product {finished product} subject to Official Control Authority Batch Release from {current value} to {proposed value}.

Q.I.b.1.b

To change the <active substance {active substance}> <<starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}> specification acceptance criteria for {attribute} from {current value} to {proposed value}.

Q.I.b.1.c

To add {attribute} to the specifications of the <active substance {active substance}> <<starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}>.<The limit is set to {value}.>

Q.I.b.1.d

To delete the <non-significant> <obsolete> specification attribute {attribute} from the specifications of the <active substance {active substance}> <<starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}>.

Q.I.b.1.e

To delete the specification attribute {attribute} from the specifications of the <active substance {active substance}> <<starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}>, which may have a significant effect on the overall quality of the <active substance> <and> <finished product>.

Q.I.b.1.f

To change the {attribute} specification acceptance criteria from {current value} to {proposed value} in the specifications of the active substance {active substance}. The change is outside the currently approved specification acceptance criteria.

Q.I.b.1.g

To change the {attribute} specification acceptance criteria for the <starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance} from {current value} to {proposed value}, which may have a significant effect on the overall quality of the <active substance> <and> <finished product>.

Q.I.b.1.h

To change the {attribute} specification acceptance criteria for the <starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance} from {current value} to {proposed value}.

Q.I.b.1.i

Change in the specifications for the active substance {active substance} from in-house to a <non-official Pharmacopoeia> <Pharmacopoeia of a third country> in absence of a <monograph in the European Pharmacopoeia> <national pharmacopoeia of a Member State>.

Q.I.b.1.j

Change in the analytical marker for the herbal active substance {substance} from {current marker} to {proposed marker}.

To widen the {attribute} acceptance criteria for the analytical marker for the herbal active substance {substance} from {current value} to {proposed value}.

Q.I.b.1.k

Change in the testing frequency of the specification attribute {attribute} of the active substance {active substance} from {current frequency} to {proposed frequency}.

Q.I.b.1.l

To replace {attribute} with {alternative attribute} in the specifications of the <active substance {active substance}> <<starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}>.

Q.I.b.2.a

Minor change to the {analytical procedure} analytical procedure for the active substance {active substance} to {brief description of the change}.

Q.I.b.2.b

To delete the {analytical procedure} analytical procedure for the active substance {active substance}.

Q.I.b.2.c

To add the <biological> <immunological> <immunochemical> {analytical procedure} analytical procedure for the active substance {active substance}.

To replace the <biological> <immunological> <immunochemical> {analytical procedure} analytical procedure with {alternative analytical procedure} for the active substance {active substance}>.

To introduce substantial change to the <biological> <immunological> <immunochemical> {analytical procedure} analytical procedure for the active substance {active substance} to {brief description of the change}.

Q.I.b.2.d

To add the {analytical procedure} analytical procedure for the active substance {active substance}.

To replace the {analytical procedure} analytical procedure with {alternative analytical procedure} for the active substance {active substance}.

Q.I.b.2.e

Minor change to the {analytical procedure} analytical procedure for the <starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance} to {brief description of the change}.

Q.I.b.2.f

To delete the {analytical procedure} analytical procedure for the <starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}.

Q.I.b.2.g

To add the <biological> <immunological> <immunochemical> {analytical procedure} analytical procedure for the <starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}.

To replace the <biological> <immunological> <immunochemical> {analytical procedure} analytical procedure with {alternative analytical procedure} for the <starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}.

To change the <biological> <immunological> <immunochemical> {analytical procedure} analytical procedure for the <starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance} to {brief description of the change}.

Q.I.b.2.h

To add the {analytical procedure} analytical procedure for the <starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}.

To replace the {analytical procedure} analytical procedure with {alternative analytical procedure} for <starting material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}.

Q.I.b.3.a

To replace the in-house reference <standard> <preparation> {substance} not covered by an approved qualification protocol.

Q.I.b.3.b

To replace the in-house reference <standard> <preparation> {substance} not covered by an approved qualification protocol. Comparability test results using current and proposed reference <standard> <preparation> material are available.

Q.I.b.3.c

To introduce a qualification protocol for the preparation {substance}.

To replace the in-house reference <standard> <preparation> material {substance} with {proposed substance}.

Q.I.b.3.d

Substantial change to the qualification protocol for the preparation {substance} to {brief description of the change}.

Q.I.b.3.e

Change to the qualification protocol for the preparation {substance} to {brief description of the change}.

To replace the in-house reference <standard> <preparation> material {substance} with {proposed substance}.

Q.I.c.1.a

Change in the immediate packaging of the non-liquid active substance {active substance} from {currently approved packaging} to {proposed packaging}.

Q.I.c.1.b

Change in the immediate packaging of the sterile liquid active substance {active substance} from {currently approved packaging} to {proposed packaging}.

Q.I.c.1.c

Change in the immediate packaging of the non-sterile liquid active substance {active substance} from {currently approved packaging} to {proposed packaging}.

Q.I.c.1.d

To delete of the immediate packaging {immediate packaging} of the active substance {active substance}.

Q.I.c.2.a

To change the {attribute} specification acceptance criteria for the immediate packaging of the active substance {active substance} from {current value} to {proposed value}.

Q.I.c.2.b

To add the {attribute} specification attribute to the immediate packaging specifications of the active substance {active substance}.<The limit is set to {value}.>

Q.I.c.2.c

To delete the <non-significant> <obsolete> specification attribute {attribute} from the immediate packaging specifications of the active substance {active substance}.

Q.I.c.2.d

To replace the {attribute} specification attribute with {alternative attribute} in the immediate packaging specifications of the active substance {active substance}.

Q.I.c.3.a

Minor changes to the {analytical procedure} analytical procedure for the immediate packaging of the active substance {active substance} to {brief description of the change}.

Q.I.c.3.b

To add the {analytical procedure} analytical procedure to the immediate packaging specifications of the active substance {active substance}.

To replace the {analytical procedure} analytical procedure with {alternative analytical procedure} in the immediate packaging specifications of the active substance {active substance}.

Q.I.c.3.c

To delete the {analytical procedure} analytical procedure from the immediate packaging specifications of the active substance {active substance}.

Q.I.c.4

To replace the {component} secondary packaging component with {proposed component} for the active substance {active substance}.

To add the {component} secondary packaging component for the active substance {active substance}.

To delete the {component} secondary packaging component for the active substance {active substance}.

Q.I.d.1.a.1

To reduce the <re-test> <storage> period of the <active substance {active substance}> <intermediate {substance} used in the manufacturing process of biological active substance {active substance}> from {current re-test/storage period} to {proposed re-test/storage period} <when stored at {define storage conditions}>.

Q.I.d.1.a.2

To introduce a <re-test> <storage> period of the <active substance {active substance}> <intermediate {substance} used in the manufacturing process of biological active substance {active substance}>. The <re-test> <storage> period is {re-test/storage period}.

Q.I.d.1.a.3

To extend the <re-test> <storage> period of the <active substance {active substance}> <intermediate {substance} used in the manufacturing process of biological active substance {active substance}> from {current re-test/storage period} to {proposed re-test/storage period} <when stored at {define storage conditions}> based on <extrapolation of stability data> <stability modelling> not in accordance with relevant stability guidelines.

Q.I.d.1.a.4

To extend the <re-test> <storage> period of the <active substance {active substance}> <intermediate {substance} used in the manufacturing process of biological active substance {active substance}> from {current re-test/storage period} to {proposed re-test/storage period} <when stored at {define storage conditions}> <supported by real time data not in accordance with an approved stability protocol > <based on extrapolation of stability data in accordance with relevant stability guidelines>.

Q.I.d.1.a.5

To extend the <re-test> <storage> period of the <active substance {active substance}> <intermediate {substance} used in the manufacturing process of biological active substance {active substance}> from {current re-test/storage period} to {proposed re-test/storage period} <when

stored at {define storage conditions}> supported by real time data in accordance with an approved stability protocol.

Q.I.d.1.b.1

To restrict the storage conditions of the <active substance {active substance}> <intermediate {substance} used in the manufacturing process of biological active substance {active substance}> from {current conditions} to {proposed conditions}.

Q.I.d.1.b.2

To change the storage conditions of the <active substance {active substance}> <intermediate {substance} used in the manufacturing process of biological active substance {active substance}> from {current conditions} to {proposed conditions}.

Q.I.d.1.c

Change to the approved stability protocol of the <active substance {active substance}> <intermediate {substance} used in the manufacturing process of biological active substance {active substance}> to {brief description of the change}.

Q.I.e.1.a

To introduce a new design space <during {affected stage X / unit operation X} in the manufacturing process> <<including the resulting <process controls> <and> <analytical procedures>> of the active substance {active substance}.

Q.I.e.1.b

To introduce a new design space concerning the {analytical procedure} analytical procedure for the <active substance {active substance}> <<starting material> <material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}>.

Q.I.e.1.c

To change the approved design space for the <active substance {active substance}> <<starting material> <material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}>.

To extend the approved design space for the <active substance {active substance}> <<starting material> <material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}>.

To change the approved design space for the {analytical procedure} analytical procedure for the <active substance {active substance}> <<starting material> <material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}>.

To extend the approved design space for the {analytical procedure} analytical procedure for the <active substance {active substance}> <<starting material> <material> <intermediate> <reagent> {substance} used in the manufacturing process of the active substance {active substance}>.

Q.I.e.2

To introduce a post-approval change management protocol intended to {intended change in the manufacturing process / intended manufacturing site} related to the manufacturing of the active substance {active substance}.

Q.I.e.3

To delete the approved change management protocol intended to {intended change in the manufacturing process / intended manufacturing site} related to the manufacturing of the active substance {active substance}.

Q.I.e.4.a

To introduce major changes to the approved management protocol intended to {intended change in the manufacturing process / intended manufacturing site} including {proposed changes} related to the manufacturing of the active substance {active substance}.

Q.I.e.4.b

To introduce minor changes to the approved management protocol intended to {intended change in the manufacturing process / intended manufacturing site} including {proposed changes} related to the manufacturing of the active substance {active substance}.

Q.I.e.5.a

To implement changes foreseen in the approved management protocol of the active substance {active substance} to {brief description of the change}.

Q.I.e.5.b

To implement changes foreseen in the approved management protocol of the active substance {active substance} to {brief description of the change}.

Q.I.e.5.c

To implement changes foreseen in the approved management protocol of the substance {active substance} to {brief description of the change}.

Q.I.e.6

To introduce a product life cycle management document related to the active substance {active substance}.

Q.I.e.8.a

Major changes to the product life cycle document related to the active substance {active substance} to {brief description of the change}.

Q.I.e.8.b

Minor changes to the product life cycle document related to the active substance {active substance} to {brief description of the change}.

FINISHED PRODUCT

Q.II.a.1.a

To <add> <remove> <the imprints> <the bossing> used for marking the finished product {specify pharmaceutical form, strength and EU#s, if needed}.

To change the composition of the ink used for marking the {specify pharmaceutical form, strength and EU#s, if needed}.

To replace the ink used for marking the {specify pharmaceutical form, strength and EU#s, if needed} with {details of new ink}.

Q.II.a.1.b

To change the <scoring> <break line> of the {specify pharmaceutical form, strength and EU#s, if needed} to divide the tablet into equal doses.

To introduce a <scoring> <break line> in the {specify pharmaceutical form, strength and EU#s, if needed} to divide the tablet into equal doses.

Q.II.a.2.a, Q.II.a.2.b

Change in the <shape> <dimension> <thickness> of the {specify pharmaceutical form, strength and EU#(s), if needed} from {current shape/dimension/thickness} to {proposed shape/dimension/thickness}.

Q.II.a.2.c

To add a new kit for the radiopharmaceutical preparation {specify radiopharmaceutical} with the fill volume of {specify vial capacity volume and solution volume in the container}. The strength remains unchanged.

Q.II.a.3.a.1

Change in the composition of the <flavouring> <colouring> of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} to <add> <remove> <replace> the {flavouring or colouring substance} <with {new flavouring or colouring substance}>.

Q.II.a.3.a.2

Change in the composition of the <flavouring> <colouring> of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} to <increase> <reduce> the amount of {flavouring or colouring substance} from {current value} to {proposed value}.

Q.II.a.3.b.1

Minor change in the quantitative composition of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} to <increase> <reduce> the amount of {excipient} from {current value} to {proposed value}.

Q.II.a.3.b.2

Change in the <qualitative> <quantitative> composition of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} to {describe in one sentence the changes in the composition; e.g. introduction/replacement of individual excipients, major readjustment of the quantities of excipients}.

Changes in the <qualitative> <quantitative> composition of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} to {describe in one sentence the changes in the composition; e.g. introduction/ replacement individual excipients, major readjustment of the quantities of excipients}> including {new substance from animal origin}, which requires an assessment of <viral safety data> <TSE risk>.

Q.II.a.3.b.3

Change in the composition of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} to {describe in one sentence the changes in the composition; e.g. introduction/replacement of individual excipients, major readjustment of the quantities of excipients}, which is supported by the bioequivalence study {introduce study reference number and title}.

Q.II.a.3.b.4

Change in the composition of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} to replace {excipient(s)} with the comparable excipient(s) {new excipient(s)}.

Q.II.a.4.a, Q.II.a.4.b, Q.II.a.4.c

Change in the <coating weight> <weight of the capsule shell> of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} from {current weight} to {proposed weight}.

Q.II.a.5

Change in the concentration of the finished product from {current} to {proposed}. The strength remains unchanged.

Q.II.a.6

To remove the <solvent> <diluent> container from the pack of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

Q.II.b.1.a

To add {name and full address} as an alternative site responsible for secondary packaging of the finished product {name} {specify pharmaceutical form, strength and EU#(s), if needed}.

To replace {name and full address} with {name and full address} as a site responsible for secondary packaging of the finished product {name} {specify pharmaceutical form, strength and EU#(s), if needed}.

To change the address of the site responsible for secondary packaging of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}, {name}, from {current full address} to {new full address}.

Q.II.b.1.b

To add {name and full address} as an alternative site responsible for immediate packaging of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To replace {name and full address} with {name and full address} as a site responsible for immediate packaging of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To change the address of the site responsible for immediate packaging of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}, {name}, from {current full address} to {new full address}.

Q.II.b.1.c

To add {name and full address} as an alternative site responsible for {activity/ies} of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To replace {name and full address} with {name and full address} as a site responsible for {activity/ies} of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To change the address of the site responsible for {activity/ies} of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}, {name}, from {current full address} to {new full address}.

Q.II.b.1.d

To add {name and full address} as an alternative site responsible for manufacturing {activity/ies} of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}, which requires <an initial> <a product specific> inspection.

To replace {name and full address} with {name and full address} as a site responsible for {activity/ies} of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}, which requires <an initial> <a product specific> inspection.

To change the address of the site responsible for {activity/ies} of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}, {name}, from {current full address} to {new full address} which requires <an initial> <a product specific> inspection.

Q.II.b.1.e

To add {name and full address} as an alternative site responsible for {activity} of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To replace {name and full address} with {name and full address} as a site responsible for {activity} of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To change the address of the site responsible for {activity} of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} {name} from {current full address} to {new full address}.

Q.II.b.1.f

To add {name and full address} as an alternative site responsible for the assembly of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} containing an integral medical device.

To replace {name and full address} with {name and full address} as a site responsible for the assembly of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} containing an integral medical device.

To change the address of the site responsible for the assembly of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} containing an integral medical device {name} from {current full address} to {new full address}.

Q.II.b.2.a

To add {name and full address} as an alternative site responsible for batch control/testing applying physicochemical and/or microbiological analytical procedures <({if needed, include the terminology used to describe each type of testing, as stated in Mod 3.2.P.3.1})> of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To replace {name and full address} with {name and full address} as a site responsible for batch control/testing applying physicochemical and/or microbiological analytical procedures <({if needed, include the terminology used to describe each type of testing, as stated in Mod 3.2.P.3.1})> of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To change the address of the site responsible for batch control/testing applying physicochemical and/or microbiological analytical procedures <({if needed, include the terminology used to describe each type of testing, as stated in Mod 3.2.P.3.1})> of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}, {name}, from {current full address} to {new full address}.

Q.II.b.2.b

To add {name and full address} as an alternative site responsible for batch control/testing applying a biological/immunological/immunochemical analytical procedure <({if needed, include the terminology used to describe each type of testing, as stated in Mod 3.2.P.3.1})> of the biological finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To replace {name and full address} with {name and full address} as a site responsible for batch control/testing applying a biological/immunological/immunochemical analytical procedure <({if needed, include the terminology used to describe each type of testing, as stated in Mod 3.2.P.3.1})> of the biological finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To change the address of the site responsible for batch control/testing applying a biological/immunological/immunochemical analytical procedure <({if needed, include the terminology used to describe each type of testing, as stated in Mod 3.2.P.3.1})> of the biological finished product {specify pharmaceutical form, strength and EU#(s), if needed}, {name}, from {current full address} to {new full address}.

Q.II.b.2.c.1

To add {name and full address} as an alternative site responsible for batch release (not including batch control/testing) of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To replace {name and full address} with {name and full address} as a site responsible for batch release (not including batch control/testing) of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To change the address of the site responsible for batch release (not including batch control/testing) of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

Q.II.b.2.c.2

To add {name and full address} as an alternative site responsible for batch release (including batch control/testing) applying physicochemical and/or microbiological analytical procedures <({if needed, include the terminology used to describe each type of testing, as stated in Mod 3.2.P.3.1})> of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To replace {name and full address} with {name and full address} as a site responsible for batch release (including batch control/testing) applying physicochemical and/or microbiological analytical procedures <({if needed, include the terminology used to describe each type of testing, as stated in Mod 3.2.P.3.1})> of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To change the address of the site responsible for batch release (including batch control/testing applying physicochemical and/or microbiological analytical procedures <({if needed, include the terminology used to describe each type of testing, as stated in Mod 3.2.P.3.1})> of the finished product {specify pharmaceutical form, strength and EU#(s), if needed}, {name}, from {current full address} to {new full address}.

Q.II.b.2.c.3

To add {name and full address} as an alternative site responsible for <batch release (including batch control/testing) applying a biological/immunological/immunochemical analytical procedure <({if needed, include the terminology used to describe each type of testing, as stated in Mod 3.2.P.3.1})> of the biological finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To replace {name and full address} with {name and full address} as a site responsible for batch release (including batch control/testing) applying a biological/immunological/immunochemical analytical procedure <({if needed, include the terminology used to describe each type of testing, as stated in Mod 3.2.P.3.1})> of the biological finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To change the address of the site responsible for <batch release (including batch control/testing) applying a biological/immunological/immunochemical analytical procedure <({if needed, include the terminology used to describe each type of testing, as stated in Mod 3.2.P.3.1})> of the biological finished product {specify pharmaceutical form, strength and EU#(s), if needed}, {name}, from {current full address} to {new full address}.

Q.II.b.3.a

Minor change in the manufacturing process of the finished product to {brief description of the change}.

Q.II.b.3.b

Major change in the manufacturing process of the finished product to {brief description of the change}.

Q.II.b.3.c

Change in the manufacturing process of the finished product to introduce the non-standard terminal sterilisation method {method}.

Q.II.b.3.d

To introduce an overage of {% of overage} of the active substance {active substance} used in the manufacture of the finished product.

To change the overage of the active substance {active substance} used in the manufacture of the finished product from of {current % of overage} to of {proposed % of overage}.

Q.II.b.3.e

Change in the <holding time> <and/or> <storage condition> of the <intermediate {intermediate}> <or> <bulk product {bulk product}> from <{current holding time} to {proposed holding time}> <and> <{currently approved storage condition} to {proposed storage condition}>.

Q.II.b.4.a

To increase the batch size <range> for the finished product {specify pharmaceutical form, strength and EU#(s), if needed} <manufactured at {name of site, if the change is site-specific}> from {approved batch size} to {proposed batch size}.

To include an alternative batch size of {proposed batch size} for the finished product {specify pharmaceutical form, strength and EU#(s), if needed} <manufactured at {name of site, if the change is site-specific}> in addition to the currently approved batch size(s) of {currently approved batch size(s)}.

Q.II.b.4.b

To decrease the batch size <range> of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} <manufactured at {name of site if the change is site-specific}> from {approved batch size} to {proposed batch size}.

Q.II.b.4.c

To <increase> <decrease> the scale of the biological finished product {specify pharmaceutical form, strength and EU#(s), if needed} <manufactured at {name of site, if the change is site-specific}> from {approved batch size} to {proposed batch size}.

Q.II.b.4.d

To <increase> <decrease> the batch size <range> of the finished product {specify pharmaceutical form, strength and EU#(s), if needed} <manufactured at {name of site, if the change is site-specific}> from {approved batch size} to {proposed batch size}.

To include an alternative batch size of {proposed batch size} for the finished product {specify pharmaceutical form, strength and EU#(s), if needed} <manufactured at {name of site, if the change is site-specific}> in addition to the currently approved batch size(s) of {currently approved batch size(s)}.

Q.II.b.4.e

To decrease the batch size <range> of <the finished product> <the {specify pharmaceutical form, strength and EU#(s), if needed}> <manufactured at {name of site, if the change is site-specific}> from {approved batch size} to {proposed batch size}.

Q.II.b.4.f

To <increase> <decrease> the scale of the biological finished product {specify pharmaceutical form, strength and EU#(s), if needed} <manufactured at {name of site, if the change is site-specific}> from {approved batch size} to {proposed batch size}. There is no change in the manufacturing process.

Q.II.b.5.a

Minor changes to the in-process limits {test}, applied during the manufacture of the finished product, from {current value} to {proposed value}.

Q.II.b.5.b

To add {test} as <a new> <an alternative> in-process control applied during the manufacture of the finished product. <The limit is set to {limit}.>

Q.II.b.5.c

To delete the <non-significant> <obsolete> in-process control {test} applied during the manufacture of the finished product.

Q.II.b.5.d

To delete the in-process control {test}, applied during the manufacture of the finished product, which may have significant effect on overall quality of the finished product.

Q.II.b.5.e

To widen the in-process limits {test}, applied during the manufacture of the finished product, from {current value} to {proposed value}.

Q.II.b.5.f

To change the {procedure} analytical procedure for the in-process control {test} applied during the manufacture of the finished product, to {brief description of the change}.

Q.II.b.5.g

To replace the in-process control {test}, applied during the manufacture of the finished product, with {alternative test}.

Q.II.c.1.a

To change the approved {attribute} specification acceptance criteria for the excipient {excipient} from {current value} to {proposed value}.

Q.II.c.1.b

To add {attribute} to the specifications of the excipient {excipient}. <The limit is set to {value}.>

Q.II.c.1.c

To delete the <non-significant> <obsolete> specification attribute {attribute} from the specifications of the excipient {excipient}.

Q.II.c.1.d

To change the {attribute} specification acceptance criteria from {current value} to {proposed value} in the specifications of the excipient {excipient}.

Q.II.c.1.e

To delete the significant attribute {attribute} from the specifications of the excipient {excipient}, which has a significant effect on the overall quality of the finished product.

Q.II.c.1.f

Change in the specifications for the excipient {excipient} from in-house to a <non-official Pharmacopoeia> <Pharmacopoeia of a third country> in absence of a <monograph in the European Pharmacopoeia> <national pharmacopoeia of a Member State>.

Q.II.c.1.g

To replace the attribute {attribute} with {alternative attribute} in the specification of the excipient {excipient}.

Q.II.c.2.a

Minor change to the approved {test} analytical procedure for the excipient {excipient} to {brief description of the change}.

Q.II.c.2.b

To delete the {test} analytical procedure for the excipient {excipient}.

Q.II.c.2.c

To introduce the <biological> <immunological> <immunochemical> analytical procedure {test} for the excipient {excipient}.

To introduce substantial change to the <biological> <immunological> <immunochemical> analytical procedure {test} for the <excipient {excipient}> to {brief description of the change}.

To replace the <biological> <immunological> <immunochemical> analytical procedure {test} with {alternative test} for the <excipient {excipient}>.

Q.II.c.2.d

To add the {test} analytical procedure for the excipient {excipient}.

To replace the {test} analytical procedure with {alternative test} for the excipient {excipient}.

Q.II.c.3.a

To replace the <excipient {excipient}> <reagent {reagent}> with a TSE risk <, used in the manufacture of {clarify use}> with {alternative excipient or reagent}.

Q.II.c.3.b

To change the source of the <excipient {excipient}> <reagent {reagent}> from {current source} to {proposed source}. The change does not present any risk of TSE contamination.

Q.II.c.3.c

To replace the <excipient {excipient}> <reagent {reagent}> with a TSE risk, not covered by a European Pharmacopeial TSE certificate of suitability<, used in the manufacture of {clarify use}> with {alternative excipient or reagent}, not covered by a European Pharmacopeial TSE certificate of suitability.

To introduce the <excipient {excipient}> <reagent {reagent}> with a TSE risk, not covered by a European Pharmacopeial TSE certificate of suitability<, used in the manufacture of {clarify use},>.

Q.II.c.4.a

Minor change in the <synthesis> <manufacture> <recovery> of the excipient {excipient} to {brief description of the change}.

Q.II.c.4.b

To change the address of the manufacturing site responsible for {activity} of the excipient {excipient} from {current name and full address} to {new name and full address}.

To change the <synthesis> <manufacture> <recovery> of the excipient {excipient}.

Q.II.c.4.c

Minor change in the manufacturing process of the excipient {excipient} to delete one of the manufacturing processes.

Q.II.c.4.d

To add {name and full address} as an alternative site responsible for the <manufacturing> <testing> of the excipient {excipient}.

To replace {name and full address} with {name and full address} as a site responsible for the <manufacturing> <testing> of the excipient {excipient}.

Q.II.d.1.a

To change the finished product specification acceptance criteria for {test} from {current value} to {proposed value}.

Q.II.d.1.b

To change the finished product specification acceptance criteria for {test} from {current value} to {proposed value}.

Q.II.d.1.c

To add {attribute} to the specifications of the finished product. <The limit is set to {value}.>

Q.II.d.1.d

To delete the <non-significant> <obsolete> attribute {attribute} from the specifications of the finished product.

Q.II.d.1.e

To change the {test} specification acceptance criteria from {current value} to {proposed value} in the specifications of the finished product.

Q.II.d.1.f

To delete the significant attribute {attribute} from the specifications of the finished product <, which has a significant effect on the overall quality of the finished product>.

Q.II.d.1.g

Changes to the dossier to comply with the provisions of an updated Ph. Eur. monograph for the finished product.

Q.II.d.1.h

To replace the currently registered <'Uniformity of Mass' method (Ph. Eur. 2.9.5)> <'Uniformity of Content' method (Ph. Eur. 2.9.6)> with the 'Uniformity of Dosage Units by Mass Variation' method (Ph. Eur. 2.9.40).

Q.II.d.1.i

Change in the testing frequency of the specification attribute {attribute} of the finished product from {current frequency} to {proposed frequency}.

Q.II.d.1.j

To replace {attribute} with {alternative attribute} in the specifications of the finished product.

Q.II.d.2.a

Minor change to the {test} analytical procedure for the finished product to {brief description of the change}.

Q.II.d.2.b

To delete the {test} analytical procedure for the finished product.

Q.II.d.2.c

To introduce the <biological> <immunological> <immunochemical> {test} analytical procedure for the finished product to {brief description of the change}.

To introduce substantial change to the <biological> <immunological> <immunochemical> {test} analytical procedure for the finished product to {brief description of the change}.

To replace the <biological> <immunological> <immunochemical> {test} analytical procedure with {alternative test} for the finished product.

Q.II.d.2.d

To add the {test} analytical procedure to the specifications of the finished product.

To replace the {test} analytical procedure with {alternative test} in the specifications of the finished product.

Q.II.d.2.e

Changes to the {test} analytical procedure for the finished product to comply with the updated general monograph in the Ph. Eur.

Q.II.d.2.f

Change in the {test} analytical procedure for the finished product to reflect compliance with the Ph. Eur. and remove reference to the outdated internal analytical procedure and analytical procedure number.

Q.II.d.3

To introduce a real-time release testing procedure in the manufacture of the finished product.

To replace the real-time release testing procedure in the manufacture of the finished product from {currently approved procedure} to {proposed procedure}.

To introduce substantial changes to a real-time release testing procedure in the manufacture of the finished product.

Q.II.e.1.a.1, Q.II.e.1.a.2

Change in the <qualitative> <and> <quantitative> composition of the immediate packaging of the finished product {specify pharmaceutical form, strength and EU#s, if needed} from {currently approved packaging} to {proposed packaging}.

Q.II.e.1.a.3

Change in the <qualitative> <and> <quantitative> composition of the immediate packaging of the sterile finished product {specify pharmaceutical form, strength and EU#s, if needed} from {currently approved packaging} to {proposed packaging}.

Q.II.e.1.a.4

Change in the immediate packaging of the finished product {specify pharmaceutical form, strength and EU#s, if needed} from {currently approved packaging} to a less protective packaging {proposed packaging}. As a consequence, <the storage conditions are being changed from {currently approved} to {proposed}> <the shelf life is being reduced from {currently approved} to {proposed}>.

Q.II.e.1.b.1

Change in the immediate packaging of the finished product {specify pharmaceutical form, strength and EU#s, if needed} to {brief description of the change}.

Q.II.e.1.b.2

Change in the immediate packaging of the sterile finished product {specify pharmaceutical form, strength and EU#s, if needed} to {brief description of the change / packaging}.

Q.II.e.1.c

To delete the immediate packaging container {description of container} for the finished product {specify pharmaceutical form, strength and EU#s, if needed}.

Q.II.e.2.a

Change in the <shape> <dimension> of the immediate packaging of the finished product to {brief description of the change}.

Q.II.e.2.b

Change in the <shape> <dimension> of the immediate packaging of the sterile finished product to {brief description of the change}.

Q.II.e.3.a, Q.II.e.3.b

Change in the {part of the packaging} of {name of the product, strength and pharmaceutical form} (EU/{insert #}) to {brief description of the change}.

Q.II.e.4.a

To change the {attribute} specification acceptance criteria for the immediate packaging of the finished product from {current value} to {proposed value}.

Q.II.e.4.b

To add {attribute} to the immediate packaging specifications of the finished product. <The limit is set to {value}.>

Q.II.e.4.c

To delete the <non-significant> <obsolete> attribute {attribute} from the immediate packaging specifications of the finished product.

Q.II.e.4.d

To replace the {attribute} with {alternative attribute} in the immediate packaging specifications of the finished product

Q.II.e.5.a

Minor change to the {test} analytical procedure for the immediate packaging of the finished product to {brief description of the change}.

Q.II.e.5.b

To add the {test} analytical procedure to the immediate packaging specifications of the finished product.

To replace the {test} analytical procedure with {alternative test} in the immediate packaging specifications of the finished product.

Q.II.e.5.c

To delete the {test} analytical procedure from the immediate packaging specifications of the finished product.

Q.II.e.6.a.1, Q.II.e.6.a.2

To add a new pack-size of {pack size} in {type of packaging} for {name of the product, strength and pharmaceutical form} (EU/{insert #}).

Q.II.e.6.b

To delete the {pack size} presentation (EU/{insert #}) for {name of the product, strength and pharmaceutical form}.

Q.II.e.6.c

To change the fill <weight> <volume> of the sterile parenteral finished product {name of the product, strength and pharmaceutical form} (EU/{insert #}) from {current fill} to {new fill}.

Q.II.e.6.d

To change the fill <weight> <volume> of the non-parenteral finished product {name of the product, strength and pharmaceutical form} (EU/{insert #}) from {current fill} to {new fill}.

Q.II.e.6.e

To add a calendar pack for the already registered presentation of {strength and pharmaceutical form} (EU/{insert #}).

To change the already registered presentation of {strength and pharmaceutical form} (EU/{insert #}) to a calendar pack.

Q.II.e.7.a

To add {name and full address} as an alternative <supplier> <manufacturer> of the {primary packaging material}.

To replace {name and full address} with {name and full address} as a <supplier> <manufacturer> of the {primary packaging material}.

Q.II.e.7.b

To add {name and full address} as an alternative site responsible for sterilisation of the {packaging component}.

To replace {name and full address} with {name and full address} as a site responsible for the sterilisation of the {packaging component}.

To change the sterilisation process of the {primary packaging material} from {current approved process} to {proposed process}.

Q.II.e.8

To replace the {component} secondary packaging component with {proposed component} of the finished product {specify pharmaceutical form, strength and EU#s, if needed}.

To add the {component} secondary packaging component of the finished product.

To delete the {component} secondary packaging component of the finished product.

Q.II.f.1.a.1

To reduce the shelf-life of the finished product {specify strength, pharmaceutical form and EU #(s) if not all presentations are affected} as packaged for sale, from {current shelf-life} to {proposed shelf-life} <when stored at {define storage conditions}>.

Q.II.f.1.a.2

To reduce the shelf-life of the finished product {specify strength, pharmaceutical form and EU #(s) if not all presentations are affected} after first opening, from {current shelf-life} to {proposed shelf-life} <when stored at {define storage conditions}>.

Q.II.f.1.a.3

To reduce the shelf-life of the finished product {specify strength, pharmaceutical form and EU #(s) if not all presentations are affected} after <dilution> <reconstitution>, from {current shelf-life} to {proposed shelf-life} <when stored at {define storage conditions}>.

Q.II.f.1.b.1

To extend the shelf-life of the finished product {specify strength, pharmaceutical form and EU #(s) if not all presentations are affected} as packaged for sale from {current shelf-life} to {proposed shelf-life} <when stored at {define storage conditions}>.

Q.II.f.1.b.2

To extend the shelf-life of the finished product {specify strength, pharmaceutical form and EU #(s) if not all presentations are affected} after first opening from {current shelf-life} to {proposed shelf-life} <when stored at {define storage conditions}>.

Q.II.f.1.b.3

To extend the shelf-life of the finished product {specify strength, pharmaceutical form and EU #(s) if not all presentations are affected} after <dilution> <reconstitution> from {current shelf-life} to {proposed shelf-life} <when stored at {define storage conditions}>.

Q.II.f.1.b.4

To extend the shelf-life of the finished product the {specify strength, pharmaceutical form and EU #(s) if not all presentations are affected} from {current shelf-life} to {proposed shelf-life} <when stored at {define storage conditions}> based on the <extrapolation> <stability modelling> not in accordance with relevant stability guidelines.

Q.II.f.1.b.5

To extend the shelf-life of the finished product the {specify strength, pharmaceutical form and EU #(s) if not all presentations are affected}, from {current shelf-life} to {proposed shelf-life} <when stored at {define storage conditions}> based on the extrapolation of stability data in accordance with relevant stability guidelines.

Q.II.f.1.c

To change the storage conditions of the biological finished product {specify strength, pharmaceutical form and EU #(s) if not all presentations are affected} from {current storage conditions} to {proposed storage conditions}.

Q.II.f.1.d

Change in the storage conditions of the <finished> <diluted> <reconstituted> product from {current storage conditions} to {proposed storage conditions}.

Q.II.f.1.e

Changes to the approved stability protocol of the finished product to {brief description of the change}.

Q.II.g.1.a

To introduce a new design space during {affected stage X / unit operation X} of the manufacturing process of the finished product {finished product}.

Q.II.g.1.b

To introduce a new design space concerning the analytical procedures {proposed analytical procedures} of the manufacturing process of the finished product {finished product}.

Q.II.g.1.c

To change an approved design space during {affected stage X / unit operation X} of the manufacturing process of the finished product {finished product}.

To extend an approved design space during {affected stage X / unit operation X} of the manufacturing process of the finished product {finished product}.

To change an approved design space concerning the analytical procedure {proposed analytical procedures} of the manufacturing process of the finished product {finished product}.

To extend an approved design space concerning the analytical procedures {proposed analytical procedures} of the manufacturing process of the finished product {finished product}.

Q.II.g.2

To introduce a post-approval change management protocol intended to {intended change(s) in the manufacturing process / intended manufacturing site} related to manufacturing process of the finished product {finished product}.

Q.II.g.3

To delete a post-approval change management protocol of the finished product intended to {intended change(s) in the manufacturing process / intended manufacturing site} related to manufacturing process of the finished product {finished product}.

Q.II.g.4.a

To introduce major changes to a post-approval management protocol intended to {intended change(s) in the manufacturing process / intended manufacturing site} including {proposed changes} related to manufacturing process of the finished product {finished product}.

Q.II.g.4.b

To introduce minor changes to a post-approval management protocol intended to {intended change(s) in the manufacturing process / intended manufacturing site} including {proposed changes} related to manufacturing process of the finished product {finished product}.

Q.II.g.5.a, Q.II.g.5.b, Q.II.g.5.c

To implement changes foreseen in a post-approval change management protocol of the finished product {finished product} to {brief description of the change(s)}.

Q.II.g.6

To introduce a product lifecycle management document related to manufacturing process of the finished product {finished product}.

Q.II.g.8.a

Major changes to the approved product lifecycle management document related to the finished product {finished product} to {description of the proposed changes}.

Q.II.g.8.b

Minor changes to the approved product lifecycle management document related to the finished product {finished product} to {brief description of the changes}.

Q.II.h.1.a

To update the information in Module 3.2.A.2 on 'Adventitious Agents Safety Evaluation' to introduce a new study related to manufacturing steps and adventitious agents for the following adventitious agents: {adventitious agent for which a risk assessment is being conducted}.

Q.II.h.1.b.1

To update the information in Module 3.2.A.2 on 'Adventitious Agents Safety Evaluation' to replace obsolete studies {name the studies} related to manufacturing steps and adventitious agents already reported in the dossier, including modifications in the risk assessment resulting in higher risk.

Q.II.h.1.b.2

To update the information in Module 3.2.A.2 on 'Adventitious Agents Safety Evaluation' to replace obsolete studies {name the studies} related to manufacturing steps and adventitious agents already reported in the dossier, including modifications in the risk assessment resulting in equivalent or lower risk.

Q.II.h.1.b.3

To update the information in Module 3.2.A.2 on 'Adventitious Agents Safety Evaluation' to replace obsolete studies {name the studies} related to manufacturing steps and adventitious agents already reported in the dossier. The risk assessment remains unmodified.

Q.III.1.a.1

To include the new Ph. Eur. Certificate of Suitability {new CEP number} for {substance}.

To include the new Ph. Eur. Certificate of Suitability {new CEP number} for {substance} to replace the ASMF issued by {ASMF Holder's name (ASMF number {EMEA or EU number})}.

<As a consequence, the following manufacturer<s> of the active substance <and active substance intermediate> <is> <are> added in Module 3.2.S.2.1: {name, full address and activity/ies performed by site(s)}>. **or**

<As a consequence, the <name> <and> <address> of the manufacturer<s> of the active substance <and active substance intermediate> <is> <are> updated as follows in Module 3.2.S.1: {clearly indicate changes related to name/full address}>. **or**

<The name and address of the manufacturer<s> of the active substance <and active substance intermediate> remain unchanged.>

Q.III.1.a.2

To update the approved Ph. Eur. Certificate of Suitability for {substance} from {current CEP number} to {new CEP number}.

<As a consequence, the following manufacturer<s> of the active substance <and active substance intermediate> <is> <are> added in Module 3.2.S.2.1: {name, full address and activity/ies performed by site(s)}.> **or**

<As a consequence, the <name> <and> <address> of the manufacturer<s> of the active substance <and active substance intermediate> <is> <are> updated as follows in Module 3.2.S.2.1>: {clearly indicate changes related to name/full address}.> **or**

<The name and address of the manufacturer<s> of the active substance <and active substance intermediate> remain unchanged.>

Q.III.1.a.3

To delete the Ph. Eur. Certificate<s> of Suitability for {substance} {CEP number<s>}.

<As a consequence, <the following manufacturer<s> of the active substance <and active substance intermediate> <is> <are> removed from Module 3.2.S.2.1: {name, full address and activity/ies performed by site(s) to be removed}.> **or**

<The name and address of the manufacturer<s> of the active substance remain unchanged.>

Q.III.1.a.4

To include the new Ph. Eur. Certificate of Suitability {new CEP number} for the non-sterile active substance {substance}.

<As a consequence, the following manufacturer<s> of the active substance <is> <are> added in Module 3.2.S.2.1: {name, full address and activity/ies performed by site(s)}.> **or**

<As a consequence, the <name> <and> <address> of the manufacturer<s> of the active substance <and active substance intermediate> <is> <are> updated as follows in Module 3.2.S.2.1>: {clearly indicate changes related to name/full address}.> **or**

<The name and address of the manufacturer<s> of the active substance <and active substance intermediate> remain unchanged.>

Q.III.1.a.5

To include the new Ph. Eur. Certificate of Suitability {new CEP number} for the herbal active substance {substance} <to replace the ASMF issued by ASMF Holder's name (ASMF number {EMEA or EU number})}>.

To update the approved Ph. Eur. Certificate of Suitability for {substance} from {current CEP number} to {new CEP number}.

<As a consequence, the following manufacturer<s> of the active substance <is> <are> added in Module 3.2.S.2.1: {name, full address and activity/ies performed by site(s)}.> **or**

<As a consequence, the <name> <and> <address> of the manufacturer<s> of the active substance <and active substance intermediate> <is> <are> updated as follows in Module 3.2.S.2.1>: {clearly indicate changes related to name/full address}.> **or**

<The name and address of the manufacturer<s> of the active substance <and active substance intermediate> remain unchanged.>

Q.III.1.b.1

To include the new Ph. Eur. TSE Certificate of Suitability {new CEP number} for {active substance}.

<As a consequence, the following manufacturer<s> of the active substance <is> <are> added in Module 3.2.S.2.1: {name, full address and activity/ies performed by site(s)}.> **or**

<As a consequence, the following manufacturer<s> of the active substance <is> <are> updated in Module 3.2.S.2.1: {clearly indicate changes related to name/full address}.> **or**

<The name and address of the manufacturer<s> of the active substance remain unchanged.>

Q.III.1.b.2

To include the new Ph. Eur. TSE Certificate of Suitability {new CEP number} for the <starting material> <reagent> <intermediate> <excipient> {substance}.

<As a consequence, the following manufacturer<s> of the active substance intermediate <is> <are> added in Module 3.2.S.2.1: {name, full address and activity/ies performed by site(s).> **or**

<As a consequence, the following manufacturer<s> of the active substance intermediate <is> <are> updated in Module 3.2.S.2.1: {clearly indicate changes related to name/full address}.> **or**

<The name and address of the manufacturer<s> of the active substance intermediate remain unchanged.>

Q.III.1.b.3

To update the Ph. Eur. TSE Certificate of Suitability for {substance} from {current CEP number} to {new CEP number}.

<As a consequence, the following manufacturer<s> of the active substance <is> <are> added in Module 3.2.S.2.1: {name, full address and activity/ies performed by site(s)}.> **or**

<As a consequence, the <name> <and> <address> of the manufacturer<s> of the active substance <is> <are> updated as follows in Module 3.2.S.2.1: {clearly indicate changes related to name/full address}.> **or**

<The name and address of the manufacturer<s> of the active substance remain unchanged.>

Q.III.1.b.4

To delete the TSE Ph. Eur. Certificate<s> of Suitability for {substance} {CEP number<s>}.

<As a consequence, the following manufacturer<s> of the active substance <and active substance intermediate> <is> <are> removed from Module 3.2.S.2.1: {name, full address and activity/ies performed by site(s) to be removed}.> **or**

<The name and address of the manufacturer<s> of the active substance remain unchanged.>

Q.III.1.b.5

To include the <new> <updated> Ph. Eur. TSE Certificate of Suitability {new CEP number} for the <active substance> <starting material> <reagent> <intermediate> <excipient> {substance}. The risk assessment with respect to potential contamination with adventitious agents is provided.

<As a consequence, the following manufacturer<s> of the <active substance> <active substance intermediate> <is> <are> added in Module 3.2.S.2.1: {name, full address and activity/ies performed by site(s)}.> **or**

<As a consequence, the <name> <and> <address> of the manufacturer<s> of the active substance <active substance intermediate> <is> <are> updated as follows in Module 3.2.S.2.1: {clearly indicate changes related to name/full address}.> **or**

<The name and address of the manufacturer<s> of the active substance remain unchanged.>

Q.III.2.a.1

Change in the specifications for the active substance {active substance} to fully comply with the <Ph. Eur.><national pharmacopoeia of the {Member State name} Member State>.

Q.III.2.a.2

Change in the specifications for the <excipient> <active substance starting material> <reagent> <intermediate> <immediate packaging material> {substance/material} to fully comply with the <Ph. Eur.><national pharmacopoeia of the {Member State name} Member State>.

Q.III.2.b

Change in the specifications of {substance} to comply with an update of the relevant <Ph. Eur. monograph> <national pharmacopoeia of the {Member State name} Member State>.

Q.III.2.c

Change in the specifications of {substance} from the national pharmacopoeia of the {Member State name} Member State to the Ph. Eur.

Q.III.2.d

Change related to a <herbal active substance> <herbal starting material> {substance} to fully comply with the <Ph. Eur.><national pharmacopoeia of the {Member State name} Member State>.

Q.IV.1.a

To add the <CE marked co-packaged device> <referenced device> {device} to be used with the medicinal product {specify strength, pharmaceutical form and EU #(s) if needed}.

To replace the <CE marked co-packaged device> <referenced device> {device} <used with the medicinal product {specify pharmaceutical form, strength and EU#s, if needed}> with {new device}.

Q.IV.1.b

To add the <CE marked co-packaged device> <referenced device> {device} to be used with the medicinal product {specify strength, pharmaceutical form and EU #(s) if needed}.

To replace the <CE marked co-packaged device> <referenced device> {device} <used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed}> with {new device}.

Q.IV.1.c

To delete the <CE marked co-packaged device> <referenced device> used with the medicinal product {specify strength, pharmaceutical form and EU #(s) if needed}.

Q.IV.1.d

Minor change to the <CE marked co-packaged device> <referenced device> {device} used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed} to {brief description of changes}.

Q.IV.2.a

To add {integral device (part)} to be used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed}.

To replace {integral device (part)} used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed} with {new integral device (part)}.

Major change to the <materials> <and> <design> <and> <performance characteristics> of the medicinal product {specify pharmaceutical form, strength and EU#s, if needed} to {brief description of the change}.

Q.IV.2.b

To add {integral device (part)} to be used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed}.

To replace {integral device (part)} used in the integral device {specify pharmaceutical form, strength and EU#s, if needed} with {new integral device (part)}.

Q.IV.2.c

To delete {integral medical device (part)} used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed}, which does not lead to the complete deletion of the <strength> <pharmaceutical form>.

Q.IV.2.d

To change the material of the {device (part)} used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed} from {current material} to {new proposed material}. The material is not in contact with the medicinal product.

Q.IV.2.e

To change the material of the {device (part)} in contact with the medicinal product in the {specify pharmaceutical form, strength and EU#s, if needed} from {current material} to {new proposed material}.

Q.IV.2.f

To add {name and full address} as an alternative <supplier> <manufacturer> of the {device (part)} to be used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed}.

To replace {name and full address} with {name and full address} as a <supplier> <manufacturer> of the {device (part)} used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed}.

Q.IV.2.g

To add {name and full address} as an alternative site responsible for sterilisation of the {device (part)} to be used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed}.

To replace {name and full address} with {name and full address} as a site responsible for sterilisation of the {device (part)} used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed}.

To change the sterilisation process of the {device (part)} supplied sterile used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed} to {brief description of the change}.

Q.IV.2.h

Minor change to the {device (part)} used in the medicinal product {specify pharmaceutical form, strength and EU#s, if needed} to {brief description of the change}.

Q.IV.3.a

Minor change in the dimension of the {device (part)} used in the finished product {specify pharmaceutical form, strength and EU#(s), if needed} from {current dimension} to {proposed dimension}.

Q.IV.3.b.1

To change the {attribute} specification acceptance criteria from {current value} to {proposed value}in the specifications of the {device (part)} used in the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

Q.IV.3.b.2

To add {attribute} to the specifications of the {device (part)} to be used in the finished product {specify pharmaceutical form, strength and EU#(s), if needed}. <The limit is set to {value}.>

Q.IV.3.b.3

To replace {attribute} with {alternative attribute} in the specifications of the {device (part)} used in the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

Q.IV.3.b.4

To change the {attribute} specification acceptance criteria from {current value} to {proposed value} of the {device (part)} used in the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To delete the {attribute} from the specifications of the {device (part)} used in the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

Q.IV.3.c.1

To add the {procedure} analytical procedure in the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To replace the {procedure} analytical procedure with {alternative procedure} in the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

To change the {procedure} analytical procedure in the {specify pharmaceutical form, strength and EU#(s), if needed} to {brief description of the change}.

Q.IV.3.c.2

To delete the {procedure} analytical procedure in the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

Q.V.a.1.a

To submit a 2nd step notification procedure for the inclusion of a new Plasma Master File Certificate (EMEA/H/PMF/{number}) granted by the EMA to {PMF holder} on {date}.

Q.V.a.1.b

To submit a 2nd step notification procedure for the inclusion of a new Plasma Master File Certificate (EMEA/H/PMF/{number}) granted by the EMA to {PMF holder} on {date}.

Q.V.a.1.c, Q.V.a.1.d

To submit a 2nd step notification procedure for the <inclusion of an <updated> <amended>> <Annual Update of the> Plasma Master File Certificate (EMEA/H/PMF/{number}) granted by the EMA to {PMF holder} on {date}.

Q.V.a.2.a

To submit a 2nd step notification procedure for inclusion a new Vaccine Antigen Master File Certificate {number} granted by the EMA to {VAMF holder} on {date}.

Q.V.a.2.b, Q.V.a.2.c

To submit a 2nd step notification procedure for the <inclusion of an <updated> <amended>> <Annual Update of the> Vaccine Antigen Master File Certificate {number} granted by the EMA to {VAMF holder} on {date}.

Q.V.b.1.a

To update the following quality section<s> of the dossier {indicate high level modules affected} to implement the outcome of the Union referral Art. {referral type} {procedure number} on {introduce in one sentence the scope of the Union referral} for the finished product {specify pharmaceutical form, strength and EU#(s), if needed}.

Q.V.b.1.b

To update the following quality section<s> of the dossier {indicate high level modules affected} linked to the outcome of the Union referral Art. {procedure number} on {introduce in one sentence the scope of the Union referral}. The finished product {specify pharmaceutical form, strength and EU#(s), if needed} was not part of the referral procedure.

CLINICAL CHANGES

C.1.a, C.1.b

To update section<s> {sections} of the SmPC <<and> section<s> {sections} of the Labelling> <and section<s> {sections} of the PL> to implement the outcome of a Union referral procedure.

C.1.c

To update section<s> {sections} of the SmPC <<and> section<s> {sections} of the Labelling> <and section<s> {sections} of the PL> to implement the outcome of a Union referral procedure. The implementation of the change(s) is further substantiated by new additional data on {specify} submitted by the holder.

C.2.a

To update section<s> {sections} of the SmPC <<and> section<s> {sections} of the Labelling> <and section<s> {sections} of the PL to {brief description of the change} following assessment of the same change for the reference product {product}.

C.2.b

To update section<s> {sections} of the SmPC <<and> section<s> {sections} of the Labelling> <and section<s> {sections} of the PL to {brief description of the change} following assessment of the same change for the reference product {product}. The implementation of the change(s) is further substantiated by new additional data on {specify} submitted by the marketing authorisation holder.

C.3.a

To update section<s> {sections} of the SmPC <<and> section<s> {sections} of the Labelling> <and section<s> {sections} of the PL> to implement the wording agreed by the <CHMP> <PRAC> <EMA> <EU competent authority> following the <outcome of the <PSUR procedure EMEA/H/C/PSUSA/{xxx}> <PASS protocol {protocol #}><PRAC signal recommendation (EPITT no{number})> <assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006> <assessment of an Urgent Safety Restriction> < joint recommendation of EU competent authorities>.

C.3.b

To update section<s> {sections} of the SmPC <<and> section<s> {sections} of the Labelling> <and section<s> {sections} of the PL> to implement the wording agreed by the <CHMP> <PRAC> <EMA> <EU competent authority> following the <outcome of the <PSUR procedure EMEA/H/C/PSUSA/{xxx}> <PASS protocol {protocol #}><PRAC signal recommendation (EPITT no{number})> <assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006> <assessment of an Urgent Safety Restriction> < joint recommendation of EU competent authorities>.

C.3.c

To update section<s> {sections} of the SmPC <<and> section<s> {sections} of the Labelling> <and section<s> {sections} of the PL> to <implement the wording agreed by the <CHMP> <PRAC> <EMA>

<EU competent authority> following the <outcome of the <PSUR procedure EMEA/H/C/PSUSA/{xxx}> <PASS protocol {protocol #}><PRAC signal recommendation (EPITT no{number})> <assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006> <assessment of an Urgent Safety Restriction> < joint recommendation of EU competent authorities>> <add a warning> <update the safety information> following the <assessment of {specify}> <based on <interim> <final> results from study {include study identifier} listed as <a <specific obligation> <imposed PASS> <obligation><PAES> in Annex II> <a category 3 study in the RMP>>; <this is a {copy the high-level description of study which should particularly mention whether the study is interventional or observational and whether the primary objective relates to efficacy or safety; the description can be omitted for non-clinical or PK studies, particularly when multiple small studies are submitted}>.

< The RMP version {#} has also been submitted.>

C.4

To update section<s> {sections} of the SmPC to <add a warning> <update the safety information> <following> <based on> <<interim> <final> results from study {include study identifier} listed as <a <specific obligation> <imposed PASS> <obligation> <PAES> in Annex II> <a category 3 study in the RMP>; this is a {copy the high-level description of study which should particularly mention whether the study is interventional or observational and whether the primary objective relates to efficacy or safety; the description can be omitted for non-clinical or PK studies, particularly when multiple small studies are submitted};< the Package Leaflet <and Labelling> are updated accordingly.>

<The updated RMP version {#} has also been submitted.>

To include significant changes to section<s> {sections} of the SmPC <<and> section<s> {sections} of the Labelling> <and section<s> {sections} of the PL> for the medicinal product {name} containing the active substances {list all active substances}, following the assessment of the medicinal product {name}, which also contains the active substance {active substance}, via procedure EMEA/{insert # of procedure}. The same wording is used for the combination product.

C.5.a

Change in the legal status of {product} from {current legal status} to {approved legal status} following the approved legal status change of the reference product {product}.

C.5.b

Change in the legal status of {product} from {current legal status} to {approved legal status} in view of {include justification}.

C.6.a

To add the new therapeutic indication {new indication}. As a consequence, section<s> {insert section(s)} of the SmPC and section<s> {insert section(s)} of the PL are updated accordingly. The updated RMP version {#} has also been submitted.

To modify the approved therapeutic indication to include <new indication/population>. As a consequence, section<s> {insert section(s)} of the SmPC and section<s> {insert section(s)} of the PL are updated accordingly. The updated RMP version {#} has also been submitted.

C.6.b

To delete the therapeutic indication {indication}. Section 4.1 of the SmPC and section 1 of the PL are updated accordingly.

C.7.a

To delete the pharmaceutical form {pharmaceutical form} from the {product} marketing authorisation (EU/{#(s)}).

C.7.b

To delete the {strength} strength from the {product} marketing authorisation (EU/{#(s)}).

C.9.a

To update <Annex II> <the RMP for {product} to version {#}> to {include a concise description of the (type of) change in the RMP/Annex II}. This change has been agreed by the <CHMP> <Competent Authority> in the outcome of {indicate variation or type of assessment}>.

C.9.b

To update <Annex II> <the RMP for {product} to version {#}> to {include a concise description of the (type of) change in the RMP/Annex II}.

To change the due date for category <1> <2> <3> studies {list studies and their identifier(s)} in the <RMP> <and> <Annex II> for {product} from {current date} to {proposed date}.

C.9.c

To update <Annex II> <the RMP for {product} to version {#}> to {include a concise description of the (type of) change in the RMP/Annex II}. This change has been agreed by the <CHMP> <Competent Authority> in the outcome of {indicate variation or type of assessment}. The implementation of the change(s) is further substantiated by new additional data on {specify} submitted by the holder.

To submit interim reports for post approval studies, which are a condition to the Marketing Authorisation.

C.10

To <include in><remove from> the Product Information the black symbol and explanatory statements for medicinal products subject to additional monitoring.

C.11

To submit the results of assessments caried out on target patient groups to comply with Article 59(3) of Directive 2001/83/EC. As a consequence, section<s> {insert section(s)} of the PL are updated accordingly.

C.12

To submit the final report from study/studies {include description of the study and study identifier(s)} <listed as a category 3 study in the RMP>. <An updated RMP version {#} has also been submitted>.