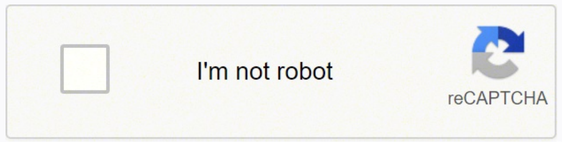

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Cmdh variation classification guideline

2.1. Introduction of a new production site for the finished product. What changes can I submit in a single Type II scope? (Classification B.II.b.1) 194; 160; For the submission of a single scope of Type II B.II, the following complex and related changes may be considered. b.1 – Addition of a new finished product manufacturing site (FP): changes to the manufacturing process, batch sizes and ongoing controls to adapt to new manufacturing site settings. Complex related changes submitted under a single Type II shall always be clearly identified on the application form as follows: a clear description of all related changes shall be provided in the precise scope. All relevant changes should be listed in the current/proposal table. Changes affecting FP not directly related to the introduction of the new production site, such as changes in excipients, specification parameters/limits for FP, container closure system, including suppliers, should be presented as additional fields of variation. Any pre-submission requests for any intended submission of complex related changes under a single scope of Type II should be addressed to Lead of the product in charge of the Type II variations. See also the question “Who is my contact person at the European Medicines Agency during the Type II variation, including extension of indications?”? That’s it. 2.2. Introduction of a new production site for an active substance. Which changes are covered by a single Type II scope? (Classification categoryB.I.a.1) 194; 160; The introduction of a new manufacturing site of an active substance supported by an MSMF shall be submitted under a single Type II scope B.I.a.1. b. of a new manufacturer of the active substance not supported by an ASMF requiring significant updates to 3.2. S shall be submitted under a single Type II scope B.I.a.1. (g). It should be noted that in cases where the introduction of the new active substance manufacturer has an impact on the level of the finished product (e.g. changes to the specification of the active substance or its analytical methods) the changes should be presented separately in the corresponding B.I.b categories and may be grouped together if related to the introduction of the new manufacturer of the active substance. See also the question “Who is my contact person at the European Medicines Agency during the Type II variation, including extension of indications?” 2.3 How should a variation of Module 3.2.S or an update of an MSMF included in Module 3 (for human use) of an authorisation be submitted placing on the market? (B.I.z) The update of Form 3.2.S may be submitted as a request for a grouped variation, if conditions 5 or 6 of Annex III to Regulation (EC) No 1408/2002 apply. 1234/2008 on changes.An update or modification of a stand-alone ASMF is not foreseen and can only be addressed in the context of a marketing authorisation. The type of change depends on the type of individual changes introduced in the updated version. The update “including amendments to the open and/or reserved part” may be submitted as a grouped application, if condition 5 of Annex III to Regulation (EC) No 1408/2002 applies. 1234/2008 on changes.However, in the event of substantial changes to the updated version of Module 3.2.S or the ASMF, it is recommended that only one Type II variation be submitted in Category B.I.z. In any event, updates to the ASMF shall be submitted by the holder of the ASMF (open and closed part to the EMA, open to the marketing authorisation holder), while the variation shall be submitted by the holder of the ASMF (open and closed part to the EMEA), open and closed part to the marketing authorisation holder. A, open to the Marketing Authorisation Holder). Marketing Authorisation Holder We encourage a close dialogue between the Marketing Authorisation Holder On the market and the ASMF owner for all changes introduced in a new version of an ASMF to avoid validation problems. Any request for pre-submission relating to the forthcoming comments on these changes should be addressed to the Product Characteristics Lead responsible for the Type II quality variations. See. Also the question is: Who is my contact at the European Medicines Agency during a Type II variation, including the extension of indications? Yeah. 2.4. How to submit an updated certificate of suitability (CEP)? (Category B.III.1)In line with the obligation on the marketing authorisation holder to keep the dossier updated, a new or updated certificate of suitability (CEP) for an active substance (AS), The excipient or starting/reagent/intermediate material used in the SA manufacturing process shall be presented as a variation. However, it is understood that only versions of the CEP (i.e. updated certificates) which have been used in the manufacturing process of a finished product batch (FP)/AS should be included in the dossier. CEP updates should be presented within the appropriate scope of classification of variations within subsection B.III.1. Each CEP update shall be presented as a range of variations, i.e. an update covering more than one version and CEP shall be presented as a grouped variation. When submitting an application for an update of an approved CEP, the marketing authorisation holder shall refer to the previously agreed version of the CEP in the "Present/Proposal" section of the application form. If one or more revisions of the SPC are omitted with the submission, the MAH shall confirm in the variation application form (Specific scope and change context section) that the substance/material of the omitted CEP versions has not been used in the manufacture of FP and/or AS during the validity of this certificate. It should also be confirmed that the changes introduced by the omitted CEP updates do not affect the quality of the AS and/or FP. In the event of non-confirmation, a negative notification of type IA may The marketing authorisation holder shall also clearly indicate in the "Present/Proposed" section all changes introduced in the CEP between the last approved version and the new revision, including any unannounced revisions. Any changes, e.g. in manufacturing sites, must be declared as additional residual solvents introduced into the CEP by subsequent updates. Example:Presentation of an updated version of the CEP for an already authorised manufacturer: R0-CEP-xxx-xx-rev. 02 when the current certificate in the dossier is: R0-CEP-xxx-xx-rev. 00. If during the validity of R0-CEP-xxx-xx-rev. 01, CEP material has been used in the manufacture of FP and/or SA, so the marketing authorisation holder must submit a grouping of two variants IA to include both certificates (rev. 01 and rev. 02) in module 3. If during the period of validity of R0-CEP-xxx-xx-rev. 01 CEP material has not been used in the production of FP and/or SA, the marketing authorisation holder shall submit only one variation type IA to include the updated certificate R0-CEP-xxx-xx-rev. 02 in module 3. The marketing authorisation holder shall also confirm in the variation application form that the material/substance of R0-CEP-xx xx-xx-rev. 01 has not been used in the production of FP and/or SA during the validity of this certificate and that the modifications introduced by the review R0-CEP-xxx-xx-rev. 01 do not affect the quality. of SA and/or FP. The marketing authorisation holder shall also clearly list in the "Present/Proposal" section of the application form all changes introduced in the CEP with revisions 01 and 02.2.5. So is it considered a control parameter or non-significant specification during the process? (Category B.I.a.4.c., B.I.c.2. c, B.II. b.5. c, B.II. c.1. c, B.II. d.1. d, B.II. e.2. c and B.IV.2. (f) Ranges of variation B.I.a.4. c, B.I.b.1. d, B.c.2. c, B.II. b.5. c, B.II. c.1. c, B.II. d.1. d, B.II. e.2. c and B.IV.2. f of the'Variation Guidelines'2013/C 223/01, deal deal deal deletion of a non-significant process control (IPC) or specification parameter. Provided that all relevant conditions and documentation requirements are met, all such variations are classified as Type IA (do-and-tell). For the categories listed above and other changes relating to specifications of active substances, excipients, finished product, packaging or measuring material or administration device, the deletion of an obsolete parameter is given as an example. For finished products, this is further exemplified by mentioning smell and taste. Although it is not possible to provide similar examples for all of the above categories, these examples serve as an indication of the types of changes considered to fall under this variation category, regardless of whether it is related to controls or process specifications. This is therefore intended to be used for really obsolete tests that are no longer part of the normal specifications for the newer products, but have remained for historical reasons in the older products. This category of variation is not intended to include changes in relation to control strategy revisions intended to minimise redundant testing of parameters and attributes (critical or non-critical) that are tested at different stages during production, or where the process/product characterisation carried out after authorisation has shown that the attribute/ parameter is non-critical. Such changes shall require regulatory assessment and shall be handled as Type IB or Type II variations, where appropriate. 2.6. When applying for a new package size, what is considered within the /outside range? (Classification B.II.e.5) The introduction of a new package size (i.e. in addition to the currently approved package sizes) should be presented as a change under the field of B.ii.e.5.a. A range is defined by the smallest to the largest approved package format (ie not from '0') for the same pharmaceutical and strength form. The package size is the same as the number of Of the pharmaceutical form (eg tablets, sachets, vials, etc.) contained in the outer packaging. For the addition of a new package when the number of packaging units falls within the range of the sizes of the packages currently approved for concentration and pharmaceutical form, applicants must submit an IAIN b.ii.e.5.a variant. 1. Packaging approved for dosing and pharmaceutical form, applicants must present a variant IB b.ii.e.5.a.2.a support of timely market introduction of new packages, the EMA accepts the following approach for € ™ Introduction of different packages that go out from the range in the context of a unique grouped presentation. The largest or smaller size of the packaging for concentration outside the interval must be classified as an IB b.ii.e.5.a.2 variant. This presentation defines the new limits of the range, so that any intermediate packaging for concentration and pharmaceutical form can be classified as an Iain variant b.ii.e.5.a.1.Esample 1The Â «Medicinal product» currently has two packs approved by 30 and 60 tablets for the pharmaceutical form Â «Film-coated tablets» and the dosage Â «20 mg.â € ™ ™ the introduction of a new pack of 120 tablets for the dosage from Â« 20 mg 'is considered Outside the range of packaging and must be classified as a b.ii.e.5.a.2 variant (IB). This package defines a new limit for the interval (30-120), so ™ the introduction of a pack of 90 tablets as a grouped presentation (or as a second) can be classified as a variation b.ii.e.5. A.1 (IAIN). The owner of the authorization to be placed on the market must therefore apply for a variation grouped by 1 x type IB â € "b.ii.ei.5.a.2 and 1x type B ii.e.5.a 1 variant.Esample 2Il Â «Medicinal product Bâ» currently has two approved Packs of 2 and 10 pre-filled syringes for the pharmaceutical form “solution for injection” for both the strengths of “20 mg” and “40 mg” The MAH is applying for four new packs: 5 pre-filled syringes for the strength of “solution for injection” “20 mgÂ”; 30 pre-filled syringes for the strength of Â”20 mgÂ”; 30 pre-filled syringes for the “40 mg” dose. For the “20 mg” strength, the introduction of a new pack of 5 pre-filled syringes for the “40 mg” strength is considered within the range of approved pack sizes (2-10) and should be classified as variation B II.e.5.a.1 (IA) and the introduction of a new Pack of 30 pre-filled syringes are considered outside the range of approved pack sizes (2-10) and should be classified as variant B.II.e.5.a.2 (IB). Pack sizes (2-10) and should be classified as variant B.II.e.5.a.1 (IA) and the introduction of a new pack of 30 pre-filled syringes is considered outside the range of approved pack sizes (2-10) and should be classified as variant B.II.e.5.a.2 (IB). introducing additional presentations or sizes for centrally approved products, each additional presentation or packaging is subject to separate fees (x additional presentations = x separate fees). Each presentation and packaging should therefore be declared as a separate variation on the variation application form under the heading “Variations included in this application”.Changes to strength, pharmaceutical form and route of administration should be submitted as an extension of a marketing authorisation.For further information on changes to the existing presentation which may trigger new EU numbers, please refer to the EMA Post-Authorisation Guidelines for Type IA, Type IB and Type IB and Type Type IB Variations.2.7. How should I present a new work cell bank (WCB)? (Classification category BIA2 a) If a new WCB is introduced using the limits / conditions specified in an approved qualification protocol, the new WCB is part of the existing quality warranty system and it is not necessary to submit a modification. If the documentation WCB in the file does not include a qualifying protocol approved for the introduction of new WCBs, the owner of the marketing authorization on the market must submit a change to introduce a qualifying protocol for the preparation of a new WCB, The owner of the authorization to be placed on the market must present a variation of type II bia2.c. Changes to an approved standard procedure (protocol) must be presented using a variation of type IB b.i.a.2.a or a variation of type II b.i.a.2.c, depending on the complexity of the change. The addition of a new WCB can be covered as part of this single variant.2.8. How to present a new reference standard for a biological medicine? If a new reference standard is introduced using the limits / conditions specified in an approved qualification protocol, the new reference standard falls within the current guarantee system of quality and not It is necessary to present a modification. If no qualification protocol has been approved and the old material is still available and the owner of the marketing authorization on the market is able to provide results of comparability tests using Both comparability standards, if no qualification protocol has been approved and the old material is no longer available and therefore a direct new / old material comparison is not possible, the holder of the authorization to the entry On the market it must present a variation of type II in bib2.d the active substance or in B.I.b.2. d for the active substance. II d.2. c for the finished product. In order to introduce a qualification protocol for the preparation of a new reference standard, the marketing authorisation holder shall: submit a type II variation under entry B.I.b.2.d for the active substance or under entry B.II.d.2.c for the finished product. Once the variation has been approved, the introduction of a new reference standard under the protocol is part of the existing quality assurance system.2.9. Provided that Module 3 is not amended, with the exception of Section 3.2.A.1 (for biologic medicinal products), the following variations (non-exhaustive list) are part of the company’s quality management system and do not require a variation of the marketing authorisation:Transfer of a marketing activity Manufacturing from one building to another on the same authorised siteTransfer of a manufacturing activity from one premises to another in the same authorised buildingTransfer of quality control activity from one building to another on the same authorised siteNew storage line identical to one already approved in an authorised premises, building, manufacturing siteNew insulator in an authorised buildingNew media or buffer preparation room in an authorised buildingChanges in the configuration of an authorised siteIf changes to Module 3 (except for section 3.2.A.1 for biologic medicinal products) are made as a result of an authorised structure, such as changes to the address of the manufacturing site Manufacturing process changes, batch size changes, etc., the MAH shall submit the appropriate variation (s). Changes in equipment used in the manufacturing process. What changes are planned by the Company Quality Assurance System (GMP)?As long as the new equipment is equivalent to the current equipment and operates according to approved process parameters, the change is part of the Company Quality Assurance System.If the introduction of new equipment an impact on the processes and details recorded in module 3 (except: 3.2.a.1 For organic medicines), the owner of the marketing authorization must submit the appropriate / e variation (s). How to update section 3.2.a.1 relating to biotechnological medicinal products? Instructions for applicants for medicinal products for human use (EUDRALEX â € "Volume 2B) establish that information on structures and equipment must be included in Appendix 3.2 .A.1 relating to biotechnological medicines. In the event that the owner of the marketing authorization intends to update this section and does not include any imminent variation concerning the short / medium-term module 3 module, the owner of the marketing authorization can be considered to present a variation of type IB (b.ii.z) .2.12 What should I consider in the event of changes to my medical device after authorization? Regulation (EC) n. 1234/2007 of the Commission (Â «Regulation on changes'» and the «Commission guidelines concerning the details of the various categories of variations, to the functioning of the procedures referred to in CAPI II, IIa, III and IV of Regulation (EC) n. 1234/2008 of the Commission and the documentation to be presented in accordance with these procedures "(Â" guidelines on changes ") define the conditions and requirements that must be satisfied with any modification (add, replacement or suppression) of a measure. Administration or administration device (classification B.IV.1). Depending on the change, the variation can be classified as type IA (in), IB or II. In consideration of the relatively short times of the variation procedures, for medical devices that at the time of placing on the market do not constitute a single integrated product and that are packaged together with the medicine, the CE mark must be presented as part of the documentation at the moment of the presentation of the variation to avoid delays. The 2.13 How do I submit the transfer of test methods for the testing of medicinal products to a new or already authorised trial site? Which variation variation variation is the category applicable and what kind of supporting documentation is foreseen? NEW Aper. 2019Although, the need to submit a variation to approve an existing QC test site for additional testing activities after the transfer of analytical tests has been completed is not specifically provided for by the current EC Guideline on the classification of variations by analogy to the expected variation of category B.I.a.1.j, B.II. b.2. b or B.II. b.2. c.3 may be required as described below in ii. Where physical, chemical and microbiological test methods are to be transferred to a new test site (i.e. not yet listed in the dossier), a variation (category B.II.b.2) is required. The documentation to be submitted is defined in the EC Guideline of the variation classification. In the case of biological, immunological or immunochemical test methods (e.g. in vivo biossays, in vitro biossays, enzyme assays, binding assays, neutralisation assays, immunochemical assays) to be transferred to a new test site or to an already approved test site, a variation of type B.I.a.1 or B.II. b.2 must be presented. The documentation should include as a minimum the protocols for transferring the method in accordance with Article 6.39 of the Eudralex Volume, Chapter 4, Article 6.39 (pre-defining acceptance criteria), from the old site to the new site (or new test laboratory). Depending on the variability of the specific method and the potential risk, quality, safety or efficacy of the product proposed by the amendment, additional data such as a summary of the results of the transfer tests of the analytical method may be required. 2.14 Do I have to register a new production site for physical import? NEW Mar 2021Member States shall ensure that the importation of medicinal products into their territory is subject to: According to Article 40 (3) of Directive 2001/83 / EC. Please note that physical import and batch certification of imported products are Operations that may take place in the same or several authorized production sites located in the Union (EEA). It is not a requirement to register in the dossier of your marketing authorization the manufacturer (i) responsible for the physical importation of the finished product, so no variation of the applications is required for changes in the physical import sites. The holder of the production and import (MIA) holder responsible for the batch certification of imported medicinal products should ensure that the site (s) of physical import is properly authorized for this operation. The physical importer must contain a MIA with a voice in Section 2.3.1 according to the format of the Union for MIAS. A technical agreement between the physical importer and the batch release site must be in place. For further information on certification by a QP and the batch version in the EU, including import, see Annex GMP 16. 16. The documentation to be submitted is defined in the EC Variation Classification Guideline. In the case of biological, immunological, or immunochemical test methods (e.g. in vivo bioassays, in vitro bioassays, enzymatic assays, binding assays, neutralisation assays, immunochemical assays) to be transferred to a new testing site or to an already ...

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