**Questions and Answers**

**Variations to the terms of marketing authorisations (MA) for medicinal products when Portugal acts as reference Member State (PT - RMS) or as concerned Member State (PT - CMS)**

Index

[1. Which are the variations that lead to the publication of SmPC and PIL in the Infomed database? 2](#_Toc170892055)

[2. What changes to the SmPC and/or PIL can be made in category A and B variations? 2](#_Toc170892056)

[3. What changes can to the SmPC and/or PIL can be made in type IA, category C variations? 2](#_Toc170892057)

[4. What kind of variations can be used to update the SmPC and/or PIL to the latest version of QRD? 3](#_Toc170892058)

[5. How should the SmPC and PIL files be submitted? 3](#_Toc170892059)

[6. How to proceed when the texts published in Infomed do not contain information that is already approved? (National procedure)? 3](#_Toc170892060)

[7. What is the approval date for the SmPC and PIL following the approval of a variation? 3](#_Toc170892061)

[8. What procedure should be followed when the MA holder intend to start the commercialisation of an already approved medicinal product? 4](#_Toc170892062)

[9. Qual a alteração a submeter para incluir, num medicamento genérico, uma indicação terapêutica do medicamento de referência cuja patente expirou (National procedure)? 4](#_Toc170892063)

[10. In which cases is paragraph 2 of Portaria n.º 377/2005, of 4 of April (in case of invalidation of any of the applications referred to in paragraphs 1 to 9 of the table attached to Portaria n.º 377/2005, Infarmed reimburses 90% of the fees to the applicant and retains 10% of fees as administrative expenses) applicable? 4](#_Toc170892064)

[11. For variations, either type IA, IAin, IB and II, is it possible to issue a new “payment´s details” in case the procedure status in Smuh-alter is “Payment not made”? 4](#_Toc170892065)

[12. Which type of variations should be submitted for the implementation of changes to the SmPC and/or PIL of a generic/hybrid medicinal product, in alignment with the texts of the reference medicinal product, if the marketing authorisation of the reference medicinal product is no longer valid? (question 3.30 of the CMDh Q&A)? 5](#_Toc170892066)

[13. In which cases does the payment of the fee according to number 9 of the table referred to in number 1 of Portaria n.º 377/2005, of 4 of April, apply? 5](#_Toc170892067)

[14. How to detail in a submission the payment of fees according to number 9 of the table referred to in number 1 of Portaria n.º 377/2005, of 4 of April? 6](#_Toc170892068)

[15. Is it mandatory in type IA B.II.d.2.a) variations to submit the document number 2 mentioned in the Guidelines on the details of the various categories of variations - "Comparative validation results or if justified comparative analysis results showing that the current test and the proposed one are equivalent.; This requirement is not applicable in case of an addition of a new test procedure." 6](#_Toc170892069)

[16. Is it possible to upgrade type IA variations? 6](#_Toc170892070)

[17. In type IA variations is it possible not to submit documentation and/or do not comply with conditions and present a justification for not fulfilling the documents/conditions and keep a variation as IA? 6](#_Toc170892071)

[18. In which circumstances is it possible to comply in type IA B.II.b.3.a variations with the condition “or the change relates to process parameter(s) that, in the context of a previous assessment, have been considered o have no impact on the quality of the finished product (regardless of the type of product and/or dosage form)”? 7](#_Toc170892072)

[19. Can a type IA variation be submitted to update the restricted part of the ASMF? 7](#_Toc170892073)

[20. Is possible to submit more than one ASMF´s version in the same variation application? 7](#_Toc170892074)

[21. Which procedure should be followed for the publication of product information for category c variations or renewals, where PT acts as CMS? 7](#_Toc170892075)

[22. How is the end of procedure of variations communicated when PT acts as CMS? 7](#_Toc170892076)

[23. When can variations where PT acts as CMS be implemented? 7](#_Toc170892077)

1. **Which are the variations that lead to the publication of SmPC and PIL in the Infomed database?**
	1. **National procedure**

All changes with an impact on the SmPC/PIL will lead to the publication of an updated SmPC and PIL in Infomed, when the SmPC and PIL of the medicinal product are already published in Infomed.

However, if there are no SmPC and/or PIL texts in Infomed yet, the publication is made only in the following variations: C.I.1 when there is complete harmonization of the SmPC/PIL, C.I.2, C.I.4, C.I.6, C.I.z – change of prescription status and C.I.z. – change to update texts following the renewal of the marketing authorisation.

* 1. **PT - CMS**

All category C variations that have an impact on the SmPC/PIL will result in the publication of an updated SmPC and PIL in Infomed.

* 1. **PT - RMS**

All variations on C category and pharmaceutical variations with an impact on the SmPC/PIL will lead to the publication of an updated SmPC and PIL, unless the medicinal product has a declaration of non-marketing in Portugal.

1. **What changes to the SmPC and/or PIL can be made in category A and B variations?**
	1. **National procedure**

In category A and B variations, only the sections of the SmPC and/or PIL corresponding to the scope of the change can be updated. Updates to either the QRD or the spelling agreement are not allowed. See also the question "**How to proceed when the texts published in Infomed do not contain information that is already approved**?".

* 1. **PT - CMS**

The SmpC and PIL from variations in categories A and B are not published in Infomed. The variations will be introduced at the time of the next category C variation with impact on the SmPC and/or PIL.

* 1. **PT - RMS**

Only changes related to the scope of the variation are allowed to be updated on SmPC and/or PIL. It is not allowed to do updates regarding to the latest version of the QRD version and/or the spelling agreement, these updates can only be made in type IB and type II category C variations.

1. **What changes can to the SmPC and/or PIL can be made in type IA, category C variations?**

**3.1 National procedure**

In type IA variations within category C, only those changes assessed in the procedure submitted, e.g. the assessment of a PSUSA, may be implemented. Other updates, such as the adaptation to the latest version of the QRD and the spelling agreement, are not allowed, with the exception, in line with Circular Informativa [051/CD/100.20.200](https://www.infarmed.pt/documents/15786/2885798/Atualiza%C3%A7%C3%A3o%2Bda%2BInforma%C3%A7%C3%A3o%2Bde%2BMedicamentos%2B%C2%BF%2BAltera%C3%A7%C3%B5es%2BC.I.z.%2BIAIN/2adbafff-d02f-4ea6-a34e-82f0f8845223) of 01/03/2019, of the term "undesirable effects" and national pharmacovigilance contacts. In this case, and if not proposed by the applicant, Infarmed implements this update in the submitted texts of SmPC and PIL, and the texts are published with this update. Other updates may only be made on type IB and type II variations of category C.

Type IA ("do and tell") variations are implemented before submission, therefore the SmPC and PIL text submitted in the application should not include text from other variations that are under assessment.

* 1. **PT - CMS**

In Type IA variations within category C, all variations approved in the Reference Member State in the relevant procedure may be introduced nationally in the SmPC/PIL.

* 1. **PT - RMS**

Only changes that have been assessed in the procedure, for example the assessment of a PSUSA. It is also allowed updates in line with Circular Informativa [051/CD/100.20.200](https://www.infarmed.pt/documents/15786/2885798/Atualiza%C3%A7%C3%A3o%2Bda%2BInforma%C3%A7%C3%A3o%2Bde%2BMedicamentos%2B%C2%BF%2BAltera%C3%A7%C3%B5es%2BC.I.z.%2BIAIN/2adbafff-d02f-4ea6-a34e-82f0f8845223) of 01/03/2019. It is not allowed updates regarding to the latest version of the QRD and/or the spelling agreement, these updates can only be made in type IB and type II category C variations.

1. **What kind of variations can be used to update the SmPC and/or PIL to the latest version of QRD?**

**4.1 National procedure**

The update to the latest QRD version may be made in type IB or type II variations of category C that are under assessment or a type IB variation in category C.I.z may be submitted for this purpose.

* 1. **PT - CMS**

The update of the SmPC/PIL should be carried out in accordance with the approved product information by the Reference Member State.

* 1. **PT - RMS**

This update can be made in type IB and type II category C variations that are under assessment or a type IB, C.I.z variation can be submitted to update the SmPC and/or PIL in line with latest QRD version.

1. **How should the SmPC and PIL files be submitted?**

**5.1 National procedure**

The electronic versions of the SmPC and PIL with track changes should be submitted in word format, and prepared in accordance with the instructions of the Circular Informativa [104/CA of 28-09-2006](https://www.infarmed.pt/documents/15786/1159643/8665276.PDF/36222033-727a-4e39-8fad-7b9eaa32bc3d). See also the question " **How to proceed when the texts published in Infomed do not contain information that is already approved**?"

**5.2 PT - CMS**

In the case of variations in category C., and according to Circular Informativa 010/CD/100.20.200 of 22/01/2021, an e-mail must be sent to infomed\_cms.post@infarmed.pt, identifying in tabular format the variations approved by the Reference Member State included in the national version of the SmPC/PIL submitted. The electronic versions of the SmPC/PIL should be sent as an attachment to the e-mail, with the aforementioned changes in track changes, in word format and prepared in accordance with the Circular Informativa [104/CA of 28-09-2006](https://www.infarmed.pt/documents/15786/1159643/8665276.PDF/36222033-727a-4e39-8fad-7b9eaa32bc3d).

In the case of variations in categories A and B., the national version of the texts should only be included in the file during the procedure, and the procedure detailed above for amendments to category C shall not apply.

1. **How to proceed when the texts published in Infomed do not contain information that is already approved**? **(National procedure)?**

This information may be added in connection with any change in categories A, B and C with an impact on the texts of the SmPC and PIL, provided that the marketing authorisation holder indicates in the texts the procedure number of the variations where the text was approved and the date of approval. To do this, this information can be entered using the "comment" tool in word.

1. **What is the approval date for the SmPC and PIL following the approval of a variation?**
	1. **National procedure**

In case of a Type II variation, after the end of the European phase, the national phase follows. In this case, the date of approval of national texts corresponds to the date of national approval of the procedure (EOP of national phase).

The approval date for the SmPC and PIL is the date of approval of the variation. In Worksharings the approval date depends on the type of variation: in type IA or IB variations, the date shall be the date of completion of the procedure by the Reference Member State; in type II variations the date corresponds to 30 consecutive days after the submission of the translations.

Note: if there are other changes with an impact on the SmPC and/or PIL in progress, the date of approval of the texts in Infomed may correspond to the date of decision of these variations.

* 1. **PT - CMS**

The date of approval of the SmPC/PIL varies according to the type of variation. In the case of a type I variations (IA or IB), the date corresponds to the date of completion of the procedure by the Reference Member State. In the case of type II variations, the date corresponds to 30 calendar days after the submission of the translations.

* 1. **PT - RMS**

The approval date for the SmPC and PIL following the approval of Type IA or IB variation is the EOP date of the procedure.

In case of a Type II variation, after the end of the European phase, the national phase follows. In this case, the date of approval of national texts corresponds to the date of national approval of the procedure (EOP of national phase).

However, the national texts (translations) can be implemented by MA holder within 30 days of their submission to the National authority, if no comments have been sent by the National authority.

In Worksharing, the approval date for national texts depends on the type of variation. If it is a type IB worksharing, the date corresponds to the date of the end of the procedure by the Reference Member State. If it is a Type II worksharing follow the above described for Type II variations.

Note: if others variations with an impact on the SmPC and/or PIL are ongoing, the date of approval on the Infomed texts may correspond to the date of decision by Infarmed relating to these variations.

1. **What procedure should be followed when the MA holder intend to start the commercialisation of an already approved medicinal product?**
	1. **PT - CMS**

The procedure detailed in Circular Informativa [143/CD/100.20.200](https://www.infarmed.pt/documents/15786/1152758/11162328.PDF/882ed504-e54b-4fd9-9202-5f1e595b7842) of 07/30/2015 and Circular Informativa [010/CD/100.20.200](https://www.infarmed.pt/documents/15786/4183417/Retifica%C3%A7%C3%A3o%2Bda%2BCI%2B191%2B16122020%2B-%2BAltera%C3%A7%C3%B5es%2Be%2Brenova%C3%A7%C3%B5es%2Bcom%2BPortugal%2BEME%2B%C2%BF%2Bpublica%C3%A7%C3%A3o%2Bde%2BRCM%2Be%2BFI%2Bno%2BInfomed/77fa4816-8399-d52c-f308-2b9789fff64e) of 01/22/2021 should be followed. The application is made by submitting in Smuh-alter a national notification at least 4 months in advance. At the same time, the assignment of registration numbers for presentations of the medicinal product may be requested.

* 1. **PT – RMS**

According to Circular Informativa [**143/CD/100.20.200**](https://www.infarmed.pt/documents/15786/1152758/11162328.PDF/882ed504-e54b-4fd9-9202-5f1e595b7842) of 30/07/2015 the MA holder should request the approval of the national product information (SmPC, PIL and labelling) at least 4 months the start of the commercialisation. This request should be done through the submission of a national notification procedure in Smuh-alter.

1. **Qual a alteração a submeter para incluir, num medicamento genérico, uma indicação terapêutica do medicamento de referência cuja patente expirou (National procedure)?**

A type IB C.I.2.a variation should be submitted.

1. **In which cases is paragraph 2 of Portaria n.º 377/2005, of 4 of April (in case of invalidation of any of the applications referred to in paragraphs 1 to 9 of the table attached to Portaria n.º 377/2005, Infarmed reimburses 90% of the fees to the applicant and retains 10% of fees as administrative expenses) applicable?**

**10.1 National procedures**

It is only applicable in the case of applications that, having been subject to analysis in the context of validation, do not meet the necessary requirements to be considered valid, being in these cases considered invalid and subject to an invalidation decision and therefore not assessed.

Considering that IA changes are not subject to validation, when the application does not meet the conditions/documentation for acceptance, it is rejected and there is no refund of the fee.

In situations of cancellation of the application, requested by the applicant on its own initiative, Infarmed does not assess the variation but does not do so on the applicant's initiative. There is no invalidation of the variation, but a withdrawal, so there is no refund of the fee.

1. **For variations, either type IA, IAin, IB and II, is it possible to issue a new “payment´s details” in case the procedure status in Smuh-alter is “Payment not made”?**

It is always possible to issue a new “payment´s details” by the applicant when the procedure status is “Payment not made” and the procedure has never been in the status “Payment validated”. Issuing a new “payment´s details” under these conditions is always the responsibility of the applicant, and Infarmed does not have any intervention at this phase.

1. **Which type of variations should be submitted for the implementation of changes to the SmPC and/or PIL of a generic/hybrid medicinal product, in alignment with the texts of the reference medicinal product, if the marketing authorisation of the reference medicinal product is no longer valid? (question 3.30 of the CMDh Q&A)?**

This issue covers situations where the marketing authorisation of the reference medicinal product is no longer valid in one or more Member States, as well as situations where the reference product is no longer valid throughout the EU.

It is not possible to change the reference medicinal product of the initial marketing authorisation application (usually linked to the generic/hybrid medicine through the bioequivalence demonstration).

When the marketing authorisation of the reference medicinal product ceases to be valid, reference may be made to another EU/EEA medicinal product within the same global marketing authorisation for the purpose of updating the product information. In this context, a global marketing authorisation means a marketing authorisation for the same medicinal product authorized in another Member State and not any other MA with the same active substance from the same MA holder, because this would amount to modifying the reference medicinal product, which is not possible.

In the MRP/DCP, if the reference medicinal product is still approved in one or more of the Member States involved, one of those medicinal products should be the primary choice as the basis for an update of the product information.

The following classification of the variation shall be chosen:

• if the holder chooses to update the product information with that of a product from the same global marketing authorisation as the reference medicinal product and the product information is harmonised between the Member States participating in the procedure or the EU/EEA Member States, a **type IB C.I.2.a** variation may be submitted

• if the holder chooses to align the product information with that of a product from the same global marketing authorisation as the reference medicinal product and the information of the chosen medicinal product is not harmonised between the Member States participating in the procedure or the EU/EEA Member States, a type II C.I.2.b variation shall be submitted

These type II variations can be submitted with a limited data package. An overview update and a solid justification for all proposed updates should be provided, including an explanation of why a particular reference text was selected for a particular update, with possible support in bibliographic references. As a general rule, the highest level of security information should be chosen.

It is the responsibility of the MAH holder of the generic/hybrid medicinal product to verify the global marketing authorisation and confirm the harmonisation. This check should be done with each future variation submission, as the adapted medicinal product can never be considered as a new reference medicinal product (therefore, if the product information is not harmonised, a C.I.2.b type II amendment should always be submitted).

If no medicinal product is available in the same global marketing authorisation (i.e. the reference medicinal product has been withdrawn throughout the EU), the MAH holder may choose to update the product information with a different medicinal product, which is not from the same global marketing authorisation as the reference medicinal product. In these cases, a type II variation C.I.4 shall be submitted, and in case amendments to different sections of the SmPC/PIL are proposed, each justified by the relevant dataset.

1. **In which cases does the payment of the fee according to number 9 of the table referred to in number 1 of Portaria n.º 377/2005, of 4 of April, apply?**

The use of number 9 of the table referred to in number 1 of Portaria n.º 377/2005, of 4 of April, is applicable to categories A.1, A.4 and A.5 variations, when the submission occurs simultaneously for all marketing authorisations held by the holder.

The fees applicable to each set of medicinal products can be consulted in the Instructions to applicants for submitting variations, renewals and MAH ownership transfers, in the table under section 8.8. Fees applicable to variation applications in categories A.1, A.4 and A.5. As regards filling in the proposed payment form in the online submission of variation applications, for the first medicinal product of each set, the applicant should select the applicable amount from number 9 from the list of available fees; for the remaining medicinal products of each set, the applicant should select the option “Free of charge or Repeated strength or pharmaceutical form” from the list of available fees.

**Medicinal products authorised by MRP/DCP**

For medicinal products authorised by MRP/DCP, it is acceptable that the submission of the variations is non-simultaneous to all marketing authorisations as the different Reference Member States may not be available to accept the variation applications at the same time.

However, the total amount of fees must be paid in a single payment, i.e. the payment form submitted must contain the medicines and files sufficient to make up the total number of fees according to number 9.

1. **How to detail in a submission the payment of fees according to number 9 of the table referred to in number 1 of Portaria n.º 377/2005, of 4 of April?**

MAH should include in the submission of all variations a copy of the list of medicines for which the variation is applicable, either in the procedure where the payment will be made, or in the other future variation applications.

The list should contain the following information in tabular format:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of the medicinal product | Strenght | Pharmaceutical form | Variation number\* | Payment form number | Description of the selected fee item in the payment form |
|  |  |  |  |  |  |

\* For national marketing authorisations identify the variation number (not the individual variation number); in the case of decentralised/mutual recognition procedures, include the variation number if already available

Example 1: A.5 variation applicable to 56 medicinal products with a national marketing authorisation

- the fee applicable to the 56 medicinal products will be 1x 9.a) + 8x 9.b) + 2x 9.c) + 45xFree of charge (11 fee items + 45 free of charge)

- the holder should complete and submit a single submission with all 56 medicinal products and the respective payment form must be filled in with all 11 applicable fee items

Example 2: A.1 variation applicable to 394 medicinal products, 23 with national marketing authorisation and 371 MRP/DCP

- the fee applicalble to the 394 medicinal products will be 1x 9.a) + 8x 9.b) + 14x 9.c) + 55x 9.d) + 316x Free of charge (78 fee items + 316 free of charge)

- the holder should complete and submit a single submission with the 23 medicinal products with a national marketing authorisation and with a number of MRP/DCP medicinal products to cover at least 55 MRP/DCP. These must be submitted simultaneously and with a single payment filled in with all 78 fee items. The following variations for the remaining MRP/DCP medicinal products can be submitted according to the availability of the respective RMS and the respective guides must be filled in with Free of charge.

1. **Is it mandatory in type IA B.II.d.2.a) variations to submit the document number 2 mentioned in the Guidelines on the details of the various categories of variations - "**C**omparative validation results or if justified comparative analysis results showing that the current test and the proposed one are equivalent.; This requirement is not applicable in case of an addition of a new test procedure."**

The submission of document number 2 is always mandatory in type IA B.II.d.2.a) variations. As these variations are for minor changes to an approved analytical procedure, the exception for new analytical procedures is not applicable.

No justification will be accepted for the non-submission of this document in the context of type IA variations. These justifications need to be assessed and can therefore be included in a type IB variation.

Failure to submit document number 2 will result in the rejection of the application in accordance with the guidance set out in Circular Informativa [125/CD/100.20.200](https://www.infarmed.pt/documents/15786/1878988/Circular%2BInformativa%2Bn%C2%BA%2B125CD100.20.200%2Bde%2B25092017.pdf/29b6e691-8b6d-4374-a050-fa3a5a2d9875) of 25/09/2017.

1. **Is it possible to upgrade type IA variations?**

Is only possible to upgrade IB variations to Type II, either isolated or as a grouping application. It is not possible to upgrade type IA variations, except when the type IA variation has been included in grouping application of type IB or II. In other words, if an isolated type IA variation has been submitted, which should be submitted as type IB, it will be rejected (see following questions), with no reimbursement of fee, since the upgrade is not possible.

1. **In type IA variations is it possible not to submit documentation and/or do not comply with conditions and present a justification for not fulfilling the documents/conditions and keep a variation as IA?**

Is not accepted on Type IA variations to justify the non-submission of documentation and/or not fulfil conditions within the scope of type IA variations. C conditions/documents cannot be marked as not applicable, unless the condition/document itself allows it .

The type IA variations should comply with all conditions and all required documentation. Any justifications regarding conditions/documents should be assessed therefore should be classified as type IB variation.

1. **In which circumstances is it possible to comply in type IA B.II.b.3.a variations with the condition “or the change relates to process parameter(s) that, in the context of a previous assessment, have been considered o have no impact on the quality of the finished product (regardless of the type of product and/or dosage form)”?**

The “context of a previous assessment” refers to a previous assessment carried out by an authority within the scope of another procedure, therefore for the condition to be fulfilled it is necessary to mention the procedure number in which the assessment has been carried out. This condition is not considered fulfilled if the “prior assessment” refers to an assessment made by the MA holder.

1. **Can a type IA variation be submitted to update the restricted part of the ASMF?**

Is not acceptable to update the restricted of ASMFs with a type IA variation, since the MA holder does not have access to the restricted part of the ASMF and therefore cannot confirm the minor nature of the update.

More information available at:

[**https://www.hma.eu/fileadmin/dateien/Human\_Medicines/CMD\_h\_/Agendas\_and\_Minutes/Minutes/2018\_12\_CMDh\_Minutes.pdf**](https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Agendas_and_Minutes/Minutes/2018_12_CMDh_Minutes.pdf)

1. **Is possible to submit more than one ASMF´s version in the same variation application?**

Each version of an ASMF should be submitted as one variation application. It is possible to submit more than one ASMF version in a grouping application with one variation for each ASMF version.

It is also possible not to register an ASMF version when no active substance produced with this ASMF version has been used. In this case, a declaration should be submitted with this information.

1. **Which procedure should be followed for the publication of product information for category c variations or renewals, where PT acts as CMS?**

This procedure is applicable to MRP/DCP marketing authorisations and national marketing authorisations in MRP worksharings.

For all category C variations, regardless they are type IA, type IB or type II, and renewals in which the SmPC and/or PIL has been updated, submitted for medicines with changes/renewals already concluded but whose information is not yet published, or resulting from the conclusion of new variations and renewals, applicants must send the following documentation to the email box infomed\_cms.post@infarmed.pt (Circular Informativa [191/CD/100.20.200](https://www.infarmed.pt/documents/15786/3464134/Altera%C3%A7%C3%B5es%2Be%2Brenova%C3%A7%C3%B5es%2Bcom%2BPortugal%2BEME%2B%C2%BF%2Bpublica%C3%A7%C3%A3o%2Bde%2BRCM%2Be%2BFI%2Bno%2BInfomed/529c908a-4f61-2e3e-207e-10a4ba6c2a69) of 16/12/2020).

* **in case of submission of national versions**:
* the national versions of the SmPC, PL and labelling, consolidating all variations/renewals impacting the texts already approved by RMS;
* declaration of compliance of national translations of the product information, according to Circular Informativa [143/CD/100.20.200](https://www.infarmed.pt/documents/15786/1152758/11162328.PDF/882ed504-e54b-4fd9-9202-5f1e595b7842) de 30/07/2015;
* list of variations/renewal corresponding to the submitted consolidated SmPC/PL/labelling national version in tabular format according to the template provided in Annex 1 of Circular Informativa [191/CD/100.20.200](https://www.infarmed.pt/documents/15786/3464134/Altera%C3%A7%C3%B5es%2Be%2Brenova%C3%A7%C3%B5es%2Bcom%2BPortugal%2BEME%2B%C2%BF%2Bpublica%C3%A7%C3%A3o%2Bde%2BRCM%2Be%2BFI%2Bno%2BInfomed/529c908a-4f61-2e3e-207e-10a4ba6c2a69) de 16/12/2020;
* **in case of non-submission of national versions:**
* declaration of non-commercialisation of the medicinal product, according to Circular Informativa Nº [143/CD/100.20.200](https://www.infarmed.pt/documents/15786/1152758/11162328.PDF/882ed504-e54b-4fd9-9202-5f1e595b7842) of 30/07/2015, in cases where marketing authorisation holders do not wish to submit national translations due to non-commercialisation of the medicinal product. This statement should be submitted together with the listing of the corresponding variations/renewal using the e-mail template in Annex 2 of Circular Informativa [191/CD/100.20.200](https://www.infarmed.pt/documents/15786/3464134/Altera%C3%A7%C3%B5es%2Be%2Brenova%C3%A7%C3%B5es%2Bcom%2BPortugal%2BEME%2B%C2%BF%2Bpublica%C3%A7%C3%A3o%2Bde%2BRCM%2Be%2BFI%2Bno%2BInfomed/529c908a-4f61-2e3e-207e-10a4ba6c2a69) of 16/12/2020.
1. **How is the end of procedure of variations communicated when PT acts as CMS?**

The conclusion of variations where PT acts as CMS is communicated by the RMS and no communication is issued by Infarmed.

1. **When can variations where PT acts as CMS be implemented?**

The implementation of PT-CMS type IB and II variations can be carried out after the RMS decision has been communicated, and there is no need to wait for the process to be completed on the Smuh-alter platform. This question doesn’t apply to type IA variations, as these are implemented before submission.