EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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FOR APPLICATION ONLY AFTER EPI GO-LIVE
FOR TIMELINES, SEE ROADMAP

Electronic product information (ePI) submission during centralised procedures

Guidance for applicants

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Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

1. Purpose and context

1.1. Purpose of this guide

This guide presents the electronic product information (ePI) submission for centrally authorised medicinal products and provides details on its practical implementation. **This guide relates only to ePI and does not replace any current regulatory guidelines.**

1.2. Preliminary requirements

This guide should be read in conjunction with other guidance available at the PLM portal.

For ePI management in the Product Lifecycle Management (PLM) Portal, the contact person(s) for the applicant will need an active EMA account, the applicant's organisation listed in Organisation Management Service (OMS) and ePI user access role(s) for the organisation assigned to the contact person's EMA account.

- EMA Account Management is the online platform to manage the EMA account
- The ePI Registration guide describes the steps to request ePI roles
- The ePI Navigation guide for applicants shows users how to create and manage ePI in the PLM portal, and it also includes a description of the various ePI statuses (*Draft*, *Submitted*, *Published*, *Archived* and *Deactivated*).

2. General principles for submission and publication of ePI

ePI only refers to Annex I (summary of product characteristics), Annex II, Annex IIIA (labelling) and IIIB (package leaflet) and does not include the other annexes to the European Commission (EC) Decision.

Until the full application of the Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (the revised 2024 general pharmaceutical legislation), ePI submission is voluntary for centrally authorised medicines. During the voluntary phase, ePI can be submitted in English and submission of any EU language translations (including Icelandic and Norwegian) of ePI is optional.[1] Submission of ePI in all languages is expected to become mandatory in future.

Once an ePI has been published, it is the responsibility and obligation of the applicant to ensure that throughout subsequent procedures the ePI (and accompanying translations if included) is kept aligned with the latest approved version of the product information (PI).

2.1. Product information in eCTD

Provision of ePI does not negate the requirement to submit product information annexes (i.e. summary of product characteristics (SmPC), annex II, labelling and package leaflet) in electronic Common Technical Document (eCTD). The relevant complete set of product information annexes must be submitted in Word format (highlighted) and PDF format (clean) in the working documents folder of the eSubmission package, and in the relevant eCTD sequence as described in both the pre-authorisation and post-authorisation guidance. To support compliance with Quality Review of Documents (QRD) template and convention, it is highly recommended that, for Marketing Authorisation Applications

[1] This does not negate the requirements laid out in the Guidance on mobile scanning.

(MAAs), applicants include the Word PI exported from the PLM portal in their working documents folder in the eCTD submission.

2.2. When to submit ePI at the PLM portal

The ePI can be submitted when associated with a regulatory procedure affecting the PI. The timing of ePI submission depends on the type of regulatory procedure, as listed in **Table 1**. below. Whenever English (EN) alone is required for PI in Word format, the same applies for ePI.

For grouped submissions (e.g. a Type IB grouped with a Type II), applicants shall follow the ePI submission requirements for the highest variation in the group and as it is currently in place for the submission of PI in Word.

ePI submission for:	Submit ePI	In case of changes, update and re-submit ePI:	Declare EPI ID via:
MAA	At the same time as submission of procedure application (EN only)	At the same time as submission of final PI translations (all languages)	eSubmission Delivery
Type IA/IAIN (inc. grouping with only Type IA/IAIN)	At the same time as submission of procedure application (all languages)	n/a or as communicated by the Agency	eSubmission Delivery
Type IB (single or worksharing) without linguistic review	At the same time as submission of procedure application (all languages)	n/a or as communicated by the Agency	eSubmission Delivery
Article 61(3) without linguistic review	At the same time as submission of procedure application (all languages)	n/a or as communicated by the Agency	eSubmission Delivery
Transfer of Marketing Authorisation (MA)	At the same time as submission of procedure application (all languages)	n/a or as communicated by the Agency	eSubmission Delivery
All other post-authorisation procedures (inc. Type IB with linguistic review and Article 61(3) with linguistic review)	At the same time as submission of final PI translations (all languages)	n/a	IRIS Industry portal

Table 1. When to (re)submit an ePI depending on procedure type

The Agency considers ePI as being submitted when all the following conditions are met:

- The ePI associated with the procedure is in *Submitted* status in the PLM portal;

Important note: Exceptionally for MAAs, ePI at the same time as submission of procedure application can be in *Draft* status. For all other procedure types and timepoints, ePI must be in *Submitted* status.

- The content of the ePI is in line with the content of the (final) Annex I, II, IIIA and IIIB submitted for the corresponding regulatory procedure(s);
- If known, procedure number(s) are entered in the procedure number field of the ePI at the PLM portal. ePIs without at least one procedure number will not be published by the Agency.

Important notes:

1. Applicants wishing to work on ePIs at any time during the procedure outside of the timepoints mentioned in **Table 1**. above may keep ePIs in *Draft* status or move ePIs to *Draft* status to allow editing.
2. If, following the assessment, changes to the PI are required, the applicant must:

- update the ePI with the relevant changes
- move the updated ePI to *Submitted* status in time for the timepoint mentioned in **Table 1**.
- include the EPI ID in the eSubmission delivery file or IRIS industry portal.

2.3. ePI and authorisation medicinal product

An ePI (and all its subsequent versions following updates in regulatory procedures) always relates to the same authorisation medicinal product/Marketing Authorisation number (Marketing Authorisation number has the format EU/1/YY/NNN).

Brand name	Marketing Authorisation number (authorisation medicinal product)	Case numbers[1]	EPI ID
Product A	EU/1/YY/123	EMA/MAA/0000123456	EPI/YY/001
Product A	EU/1/YY/123	EMA/VR/0000234567[2] EMA/VR/0000245790[2]	EPI/YY/006
Product A	EU/1/YY/123	EMA/X/0000345678	EPI/YY/010

Table 2. An ePI relates to one authorisation medicinal product (Marketing Authorisation number). Each time an ePI is updated in one or several (parallel) regulatory procedures, a new ePI version with a new EPI ID is created.

[1] Case numbers refer to marketing authorisation applications and post-authorisation regulatory procedures that affect the product information.
[2] Regulatory procedures concluding at the same time (e.g. same Opinion date) that affect the product information. Changes to the product information from two procedures are in this example consolidated in one ePI (see section 5.1. below).

2.3.1. Linking an authorisation medicinal product to ePI at PLM portal

Before submitting an ePI, the applicant must link an authorisation medicinal product to the ePI at the PLM portal. The correct authorisation medicinal product–ePI link ensures that the correct ePI is published on time and for the correct regulatory procedure.

Important note: An ePI cannot be moved to *Submitted* status at the PLM portal unless it has been linked to an authorisation medicinal product.

2.4. ePI in eSubmission and IRIS Industry portal

This section will soon be updated to provide detailed guidance on how the applicant will communicate the relevant EPI ID to the Agency.

2.5. Declaration on submission

Changing the ePI status to *Submitted* officially sends the ePI to the Agency. To change the status to *Submitted*, a declaration must be completed and signed by a signatory who is an authorised contact for the product, or an alternative company representative.

It is the responsibility of the applicant to ensure that the ePI in *Submitted* status is identical in content to the final Annexes I, II, IIIA and IIIB submitted for the corresponding regulatory procedure(s)[2] and intended for publication on the EPAR page of the respective medicinal product.

2.6. Procedure number(s)

The procedure number field of the ePI should be completed or edited by the applicant as soon as the number is known. The Agency will publish the ePI only if it has at least one procedure number.

Changes from several regulatory procedures can be consolidated in one PI/ePI; in this case, all the procedure numbers must be listed in the procedure number field of the ePI.

2.7. ePI publication

If the outcome of the procedure is favourable, the ePI will be published by the Agency (i.e. moved to *Published* status in the PLM portal and made publicly available from the ePI repository via the application programming interface, or API) at the latest by the time of EPAR publication.

2.8. Version of the QRD template used to create ePI

When creating the first ePI in the context of a MAA, the applicant can choose any valid version of the QRD template. The ePI and the Word PI submitted in the application dossier must follow the same version of the QRD template.

When creating the first ePI in the context of a post-authorisation procedure, or when updating an existing ePI, the applicant must select the same version of the QRD template as the PI in Word or PDF format submitted for or approved during that procedure.

3. Small and medium-sized enterprises (SMEs)

For MAAs, the SME applicant is responsible for creating and submitting the ePI – in English only – at the PLM portal to coincide with the submission of the dossier in eCTD (see also *4.1 First-time creation in a marketing authorisation application*).

In case of favourable outcome, by Day +25 after Opinion, the SME applicant can optionally update the ePI in the PLM portal to include the Norwegian and Icelandic translations. The Agency will issue

[2] As listed in the procedure number field of the ePI.

additional guidance, in due course, on how the PI translations for the other EU languages will be handled on behalf of the SME applicants.

For the post-authorisation phase, the SME applicant should follow the guidance under sections 4.2 and 5 below.

4. First-time creation of ePI

4.1. First-time creation in a marketing authorisation application

ePI can be created for the first time during a marketing authorisation application.

When ePI is created for a Marketing Authorisation number **for the first time**, the ePI must be completed and kept in *Draft* status at the PLM portal **at the time of the initial eCTD submission** (see **Table 1**.). The content of the ePI should be identical to the content of the PI included in the eCTD Module 1.
In case of favourable outcome, the applicant shall update the content of the ePI, as applicable, in line with the final PI in Word format and move the ePI to *Submitted* status at the PLM portal, at the same time as submission of final PI translations.

4.2. First-time creation for an authorised medicine

ePI can be created for the first time for a Marketing Authorisation number that has not previously had an ePI during a post-authorisation procedure that affects the PI of the medicine. The ePI must be completed and moved to *Submitted* status at the PLM portal at the timepoints indicated in **Table 1**., depending on the procedure type.

4.3. First-time creation outside a regulatory procedure

For authorised medicines where an applicant wishes to create and publish an ePI but no suitable upcoming procedures are foreseen within the next six months, with the prior agreement of EMA and for a limited time period[3], an ePI can be submitted outside a regulatory procedure.

Important: The ePI submitted in the PLM portal must follow the same version of the QRD template as the latest approved version of the PI in Word/PDF format. The content of the ePI must also be identical to the latest approved version of the PI.

1. Complete the form to request creation outside a regulatory procedure, providing the following information:

- Medicine name and Marketing Authorisation number
- Date of the next expected regulatory procedure affecting the PI
- The number of the latest approved procedure affecting the PI (indicate all procedure numbers if changes from several procedures were consolidated in the same PI)
- ePI in EN only or EN and EU languages[4]

2. Once you have received email confirmation that creation outside a regulatory procedure will be accepted, create and submit ePI within two weeks.

[3] At the discretion of the ePI team.
[4] For a limited time period and to facilitate the transition to a fully multilingual ePI, it is acceptable for applicants to submit ePI in EN and optionally one (or several) additional EU languages.

3. In the procedure number field, enter the number(s) of the procedure(s) that last affected the product information of the medicine.
4. Email ePI@ema.europa.eu providing EPI ID.
5. ePI will be published within 2 weeks of submission. Once it is published, the applicant must maintain the ePI up-to-date in all subsequent procedures affecting the PI.

5. Updating ePI

In case an ePI is already published for a Marketing Authorisation number, and a post-authorisation procedure affects any of the Annexes I, II, IIIA and IIIB, **a new version of the ePI must be created and submitted**: at the PLM portal, the applicant must choose the option *'Update existing ePI'*.

Table 1. above outlines when the applicant is required to submit the updated ePI, depending on the procedure type.

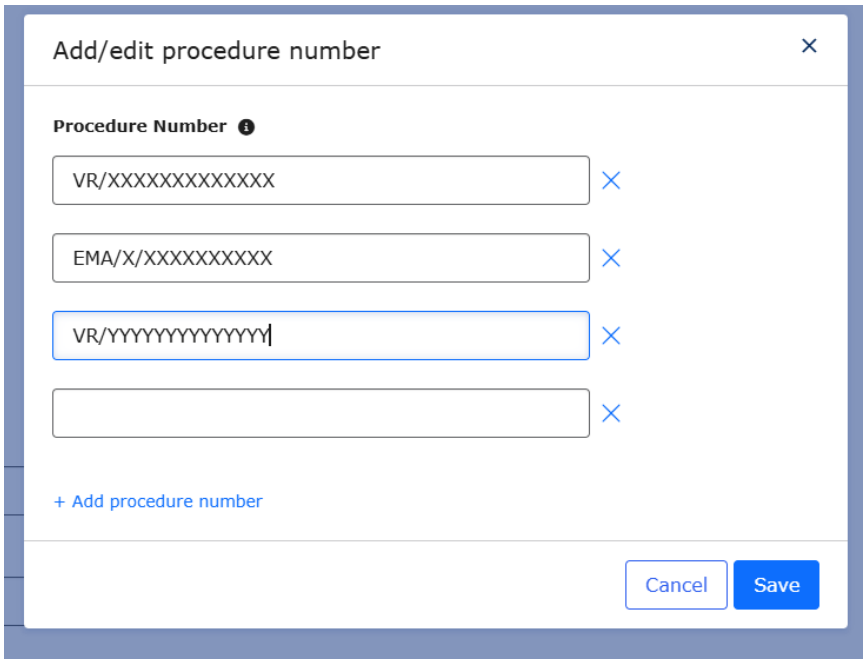
Important notes:

- At the PLM portal, the *'Update existing ePI'* option **must** be used for updating *Published* ePIs during post-authorisation. This is required in order to ensure correct ePI versioning.
- If an updated version of the existing ePI is not submitted, the regulator will move the existing, *Published* ePI to *Archived* status to avoid the situation where the published ePI for an authorised medicine is out of date.
- If ePI translations are provided, the translations must also be kept up to date and aligned with the EN ePI.

5.1. Regulatory procedures affecting the PI and concluding at the same time

Changes from more than one procedure should be consolidated in one ePI using the same guidelines currently in place for the PI in PDF format, as set out in the Post-authorisation guidance. There are however some additional points to consider:

- When combining several procedures in one ePI, the numbers of all procedures must be listed in the procedure number field at the PLM portal for that ePI.



- ePIs that have been submitted but are no longer required to be published by the Agency (for example, because the changes have been included in the ePI of a concurrent procedure in a consolidated ePI) should be moved to *Deactivated* status by the applicant.
- See also section 2.4. on how to communicate the EPI ID of a consolidated ePI to the Agency.

5.2. Super-grouping (grouped variations for several products)

In case of several products affected by a grouping of variation applications, the ePI of each concerned medicine must be updated accordingly. The procedure number field of each ePI must reflect the number of the grouped variation application.

Medicines that already have an ePI may be included in the same super-grouping as medicines for which an ePI has not yet been published.

5.3. Worksharing (where EMA is the reference authority, i.e. the procedure includes at least one CAP)

In case of several products affected by a worksharing application, the ePI of each concerned medicine must be updated accordingly. The procedure number field of each ePI must reflect the product-level number for the worksharing application (in the format EMEA/H/C/prod_nb/WSnnnn/nn).

Medicines that already have an ePI may be included in the same worksharing procedure as medicines for which an ePI has not yet been published. **Table 1.** above outlines when the applicant is required to submit the ePI, depending on the procedure types included in the worksharing application.

Important note: Applicants may make use of the 'Add Co-author from outside my organisation' functionality in the PLM portal if, due to agreements in place, the ePI must be updated by a user from another organisation.

The Agency will publish the ePIs of the CAPs concerned by the worksharing procedure; in case an ePI has also been submitted for the NAP/MRP/DCP products involved in the same worksharing, the relevant national medicines agency will publish the ePI for these medicine(s).

6. Suspension

6.1. Suspension of a marketing authorisation

If an ePI exists for the medicine: Two scenarios are possible:

Scenario A: The applicant has created an ePI for the medicine, but it has not been published by the regulator (i.e. the ePI is in *Draft* or *Submitted* status).

No action is required from the applicant until the regulatory procedure imposing the suspension has been concluded.

If the regulatory procedure has concluded with suspension as the final outcome, the applicant must move any *Submitted* ePI to *Deactivated* status within 15 working days of the CHMP Opinion.

Scenario B: The applicant has created an ePI for the medicine and it has been published by the regulator. In such case, the ePI will remain published in the ePI repository and available via the API. If, in addition, there are also previous versions of the ePI in *Archived* status, these versions will stay as-is. No further action is required from the applicant.

6.1.1. Lifting of a suspension

On the lifting of a suspension, no action is required from the applicant regarding published ePI since ePIs remain in *Published* status throughout a suspension.

ePIs can continue to be submitted for any ongoing or finalised post-authorisation procedures as per usual guidance. As usual, applicants must select 'Update existing ePI' when updating at the PLM portal, in order to maintain correct ePI versioning (see Section 5 above).

7. Transfer of marketing authorisation

Before submission of the application for transfer, both the transferor and the transferee must complete the steps in **Table 3.** below in order to arrange the transfer of the published ePI for the medicine. These steps are in addition to the responsibilities of the transferor and transferee detailed in the Post-authorisation guidance.

Required actions for the transferor	Required actions for the transferee
Using the option '*Update existing ePI',* create a new ePI based on the *Published* ePI for the medicine.	Designate a contact person as responsible for maintaining the ePI up-to-date.
Using the functionality '*Add co-author from outside your organisation*', add the contact person designated by the transferee to take over the responsibility of maintaining the ePI up-to-date.	The designated contact person must apply for and be granted the ePI Applicant Manager role in the PLM portal for both the ORG-ID of the transferor and of the transferee.
Grant the ePI Applicant Manager role to the contact person designated by the transferee	
Update the procedure number field for the new ePI with the procedure number of the transfer application, when known.	
Submit the new ePI in the PLM portal.	

Table 3. ePI-related responsibilities of the transferor and transferee before submitting the application for transfer of MA.

At End of procedure (upon issue of Commission Decision granting the transfer of marketing authorisation): The transferor and the transferee must complete the following actions:

Required actions for the transferor	Required actions for the transferee
Deactivate all ePIs in *Submitted* status for the concerned medicine, with the exception of the ePI related to the transfer application.	
Update the ePI submitted for the transfer application with changes agreed during the procedure (if any)	
	Open a ticket via the EMA Service Desk requesting the transfer of the ePI from the ORG-ID of the transferor to the ORG-ID of the transferee.

Table 4. ePI-related actions of the transferor and the transferee after the issue of the EC Decision

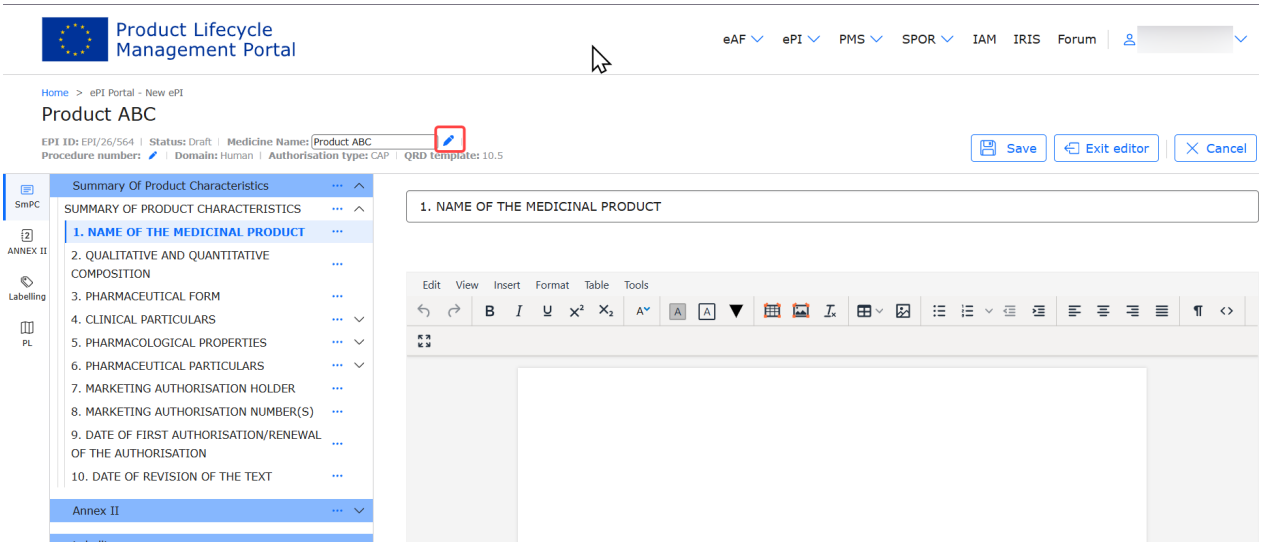
The Agency will publish the ePI associated with the transferee after the issue of the EC Decision granting the transfer.

8. Change in the (invented) name of the medicine

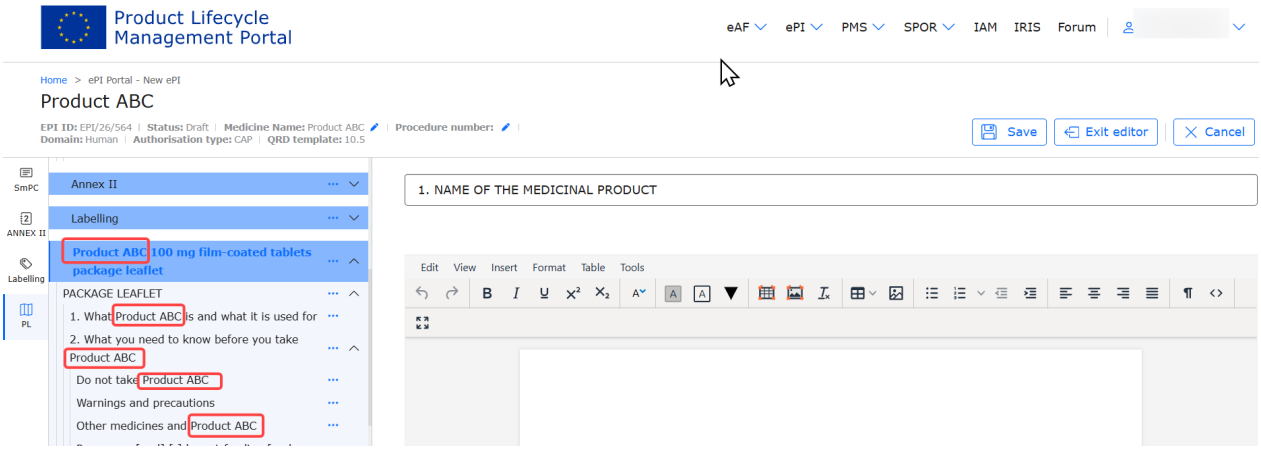
Updating the invented name of a medicine takes place in the context of a regulatory procedure, as described in Section 5: Updating ePI.

Some additional important changes to ePI are needed to ensure the new name is reflected throughout the ePI:

- The applicant should update the medicine's name on the ePI by clicking on the pencil symbol next to the medicine name field and changing to the new name of the medicine. Click the pencil icon again to save the new name. (The pencil symbol is only visible for ePIs in status *Draft* or *Submitted*).



- The name of the medicine should also be updated in the body of the ePI, including the section headings of the package leaflet and the documents names where relevant.



9. Referral procedures

In case the outcome of a referral procedure introduces changes to the PI of a CAP, the relevant ePI should be updated and submitted as per the requirements laid out in sections 2.2 and 5 above.

If the outcome of the referral procedure results in the suspension of the marketing authorisation of the medicine, see section 6 on how to manage the relevant ePI in this case.

It is possible that the referral procedure also affects the product information of medicines authorised at national level (via the MRP/DCP or purely national authorisation procedures). In this case, the update and publication of the ePI for these medicines (if required) will be handled by the respective NCAs.

10. Withdrawal

10.1. Withdrawal of a marketing authorisation application

As soon as the withdrawal has been notified to the Agency (within 15 working days), the applicant must move the ePI to *Deactivated* status.

10.2. Withdrawal of a post-authorisation procedure

If the applicant has created one/several ePIs for the withdrawn procedure, (i.e. the ePIs are in *Submitted* status), the applicant must move all related ePIs to *Deactivated* status, as soon as the withdrawal has been notified to the Agency (within 15 working days). The applicant will also ensure that the number of the withdrawn procedure will not be included in the procedure number field of other ePIs related to other ongoing or recently finalised procedures.

10.3. Withdrawal of a marketing authorisation

The applicant shall move all ePIs that are in *Submitted* status to *Deactivated* status, as soon as the withdrawal has been notified to the Agency (within 15 working days). If an ePI has already been published for the medicine, the ePI will remain published in the ePI repository and available via the API. If, in addition, there are also previous versions of the ePI in *Archived* status, these versions will remain as-is.

11. Refusal

11.1. Refusal of a marketing authorisation application

Within 15 working days after the unfavourable opinion, the applicant must change the status of the ePI to *Deactivated*. If the applicant requests a re-examination, the ePI can remain in any status pending the final outcome of the procedure.

11.2. Refusal of a post-authorisation procedure

If the applicant has created one/several ePIs for the refused procedure, (i.e. the ePIs are in *Submitted* status), the applicant must move all related ePIs out of *Submitted* status (to *Draft* or *Deactivated*), within 15 working days after the negative CHMP opinion or notification has been issued.

If the applicant requests a re-examination, the ePI(s) can remain in any status pending the final outcome of the procedure. If the final outcome is unfavourable: within 15 working days after the unfavourable opinion, the applicant must change the status of the ePI(s) to *Deactivated*.

The applicant will also ensure that the number of the refused procedure will not be included in the procedure number field of other ePIs related to other ongoing or recently finalised procedures.

12. Correction of errors in ePI

- If the ePI containing the error has not been published (i.e. the ePI is in status *Submitted* or *Draft):* the applicant can edit the content of the ePI via the web-based text editor and introduce the correction, or import the correct content via FHIR import, as required. (In order to edit the content of an ePI in *Submitted* status, the applicant must first move the ePI in status *Draft*).
- If the ePI containing the error has been published (i.e. the ePI is in *Published* or *Archived* status): the applicant must contact the product team in the first instance. The same process for correction of errors in the Word/PDF PI will be followed for ePI.