16 December 2025
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Human Medicines Division

NRG form – Questions & Answers

Guide to completing the electronic Name Review Group (NRG) Form: practical and technical considerations.

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Executive summary

The electronic Name Review Group (NRG) Form was introduced in 2013, accompanied by a Questions and Answers (Q&A) document designed to address potential technical issues. Since its introduction, an analysis of recurrent queries received from applicants has highlighted the need to broaden the scope of this resource.

This first revision of the Q&A document provides additional guidance on previously unaddressed topics, including instructions on accessing, completing, and submitting the electronic NRG Form. Updated sections are clearly marked as "NEW" or "Rev.", along with the relevant publication date. For comprehensive guidance on the submission and review of proposed (invented) names by the NRG, users should continue to consult the *Guideline on the acceptability of names for human medicinal products processed through the centralised procedure*. If your query regarding the access, completion or submission of the NRG Form is not addressed in this document, please contact the NRG secretariat at NRG@ema.europa.eu.

1. Introduction

1.1. The (invented) name review process - NEW Dec 2025

In accordance with Article 6 of Regulation (EC) No 726/2004, "**each application** for the authorisation of a medicinal product (…), otherwise than in exceptional cases relating to the application of the law on trade marks, shall include the use of a **single name** for the medicinal product". Proposals for invented names, as well as names presented under the construction 'INN + company name/trade mark' must be submitted to the EMA for review.

The EMA has established a process performed by the NRG to assess the acceptability of (invented) names for medicinal products. In order to request the review of proposed (invented) names, applicants/marketing authorisation holders (MAHs) are required to complete and submit an Electronic NRG Form (dynamic PDF format).

1.2. The electronic NRG Form - Rev. Dec 2025

Since its introduction in January 2013, the electronic NRG Form has replaced previous Word-based and paper forms, helping to streamline the processing of name review requests, particularly the upload of data into the NRG database.

IMPORTANT: Do not open the form directly in a web browser, as this will generate an error and prevent access to the content. The form must be opened using Adobe Reader (free version) or Adobe Acrobat (Standard, Pro, or Pro Extended) version 9.1.0 or higher.

Completed NRG Forms should be submitted to EMA via **Eudralink or by email** to NRG@ema.europa.eu. When submitting a name review request, please ensure that:

1. The NRG Form is submitted as an interactive/editable Adobe PDF file.
2. All supporting documents are attached separately to the email/Eudralink message (not in folders or zip files).
3. Submission deadlines set by the NRG are met. For details, see Pre-authorisation guidance>Q&A: 3.1 Product name, product information and prescription status>3.1.2

IMPORTANT: only **one NRG Form** should be submitted per Eudralink message or email. For example:

- a **name request form** and a **justification form** for the same product must be submitted separately.
- Name request forms for a product and its duplicate application must always be submitted as separate name applications.

1.2.1. Types of review requests processed by the NRG and required documentation - NEW. Dec 2025

The table below outlines:

1. all types of name review requests processed by the NRG,
2. whether the applicant/MAH is required to submit an NRG Form,
3. whether additional supportive documentation should or may accompany the submission.

Types of requests processed by the NRG	Is it required to submit an electronic NRG Form?	Which supportive documentation should always accompany the submission?*
Procedure to **submit a new name review request.** Applies to: names not previously reviewed by the NRG; reviewed names for which the validity has expired.	**Yes;** use the radio button at the top of the form and select 'Request Form'	1.Draft summary of product characteristics (SmPC) or product profile or Investigator's Brochure
Procedure to **reconfirm an accepted invented name** (i.e. extension of expiry date by 1 year). Applies to: names accepted by the NRG for which the validity has not expired yet.	**Yes;** use the radio button at the top of the form and select 'Request Form.' Within the section 'Reconfirmation', indicate that it is a request for reconfirmation.	1.Draft SmPC or product profile or Investigator's Brochure
Procedure to **re-use an accepted invented name.** Applies to: names accepted by the NRG for which the validity is not expired yet.	**Yes;** use the radio button at the top of the form and select 'Request Form.' Within the section 'Proposed (Invented) Name(s)', indicate that it is a re-use.	1.Draft SmPC or product profile or Investigator's Brochure
Procedure to **justify the retention of a name** rejected by the NRG	**Yes;** use the radio button at the top of the form and select 'Justification Form.'	1. Draft SmPC or product profile or Investigator's Brochure 2. Comprehensive justification, e.g. name safety report, assessment of potential for harm for the patient in case of mix-up. This report is to be provided up to 2 weeks post-deadline.
Procedure to **withdraw an accepted invented name**	**No;** to notify the intent to withdraw a name, please send an email to: NRG@ema.europa.eu	It is required to describe the grounds that may justify the withdrawal request. Please check whether providing supporting documentary evidence applies, as specified in the *Guideline on the acceptability of names for human medicinal products processed through the centralised procedure* (see section 6.1)

* Other relevant information may be submitted, e.g. justification for deviation from the guideline, justification for inclusion of a qualifier, name safety reports, justification for withdrawal of an accepted name, proof of MAA submission, rationale behind the use of multiple applications, description of a medical device, proof of orphan status designation, letter authorising the submission on behalf of the MAH, NRG outcome letter. For more information, see the *Guideline on the acceptability of names for human medicinal products processed through the centralised procedure*

2. Accessing the NRG Form

Q.1. Where can I find the NRG Form and how should I open it? - Rev. Dec 2025

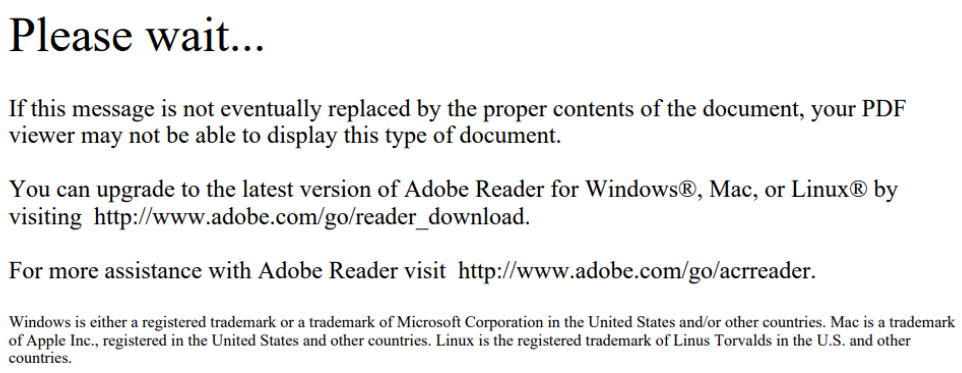
EMA ensures that the latest version of the NRG Form is always available for applicants.

A: To **download** the most recent version of the form, please use the following link: Name Review Group form

B: The form must be opened using **Adobe Reader** (free version) or **Adobe Acrobat** (Standard, Pro, or Pro Extended) version 9.1.0 or higher.

The latest free version of Adobe Reader can be downloaded from Adobe's official website: Adobe Reader web page.

IMPORTANT: Do **not** open the form directly in a web browser, as this will generate the error message below and prevent access to the content. Always use Adobe Reader or Adobe Acrobat.



Please wait...

If this message is not eventually replaced by the proper contents of the document, your PDF viewer may not be able to display this type of document.

You can upgrade to the latest version of Adobe Reader for Windows®, Mac, or Linux® by visiting http://www.adobe.com/go/reader_download.

For more assistance with Adobe Reader visit http://www.adobe.com/go/acrreader.

Windows is either a registered trademark or a trademark of Microsoft Corporation in the United States and/or other countries. Mac is a trademark of Apple Inc., registered in the United States and other countries. Linux is the registered trademark of Linus Torvalds in the U.S. and other countries.

Q.2. When opening the NRG Form, what should I do if I receive the message *'Some features have been disabled to avoid potential security risks. Only enable these features if you trust this document'?* - Rev. Dec 2025

The first time the form is opened, the following banner may appear at the top of the window:

Click the 'Options' button and **select 'Trust this document always'.**

IMPORTANT: If your local IT policy forbids you from 'trusting the document', it is recommended that you contact your local IT service desk and request that they allow the form access to the following URLs: https://spor.ema.europa.eu/rmswi/#/lists/100000000002/terms ; https://spor.ema.europa.eu/rmswi/#/lists/100000073345/terms ; https://spor.ema.europa.eu/rmswi/#/lists/200000000004/terms

These web services locations managed by EMA enable many of the forms' fields, searches and drop-down lists to be populated dynamically. Without access to these locations, the NRG Form **cannot** be fully completed.

3. Guidance for completing the NRG Form

3.1. Mandatory fields

Q.3. Can I leave mandatory fields empty?

The inclusion of mandatory fields and the application of validation rules are essential to ensure the quality of submissions and to facilitate efficient processing of information by all relevant parties. Therefore, it is strongly recommended that all mandatory fields be completed. In cases where, for justified reasons, the required content is unavailable for a specific field, please enter a single space or a full stop to meet the minimum validation requirements.

Q.4. How can I see which fields are mandatory?

To check which fields are mandatory, click the button 

on the last page of the form as soon as you open the document. All mandatory fields are then highlighted and are accessible through the validation errors window.

3.2. Drop-down lists and search fields - Rev. Dec 2025

Drop-down lists and search fields within the NRG Form are dynamically populated with information from EMA's Referentials Management Services (RMS) and enabled via the web location RMS Web UI

RMS replaces the European Union Telematics Controlled Terms (EUTCT) system as the provider of referentials lists and terms (such as routes of administration, pharmaceutical forms) in multiple languages.

Q.5. Why do the drop-down lists for certain fields not function?

Drop-down lists/search fields do not work correctly when the enhanced security settings in Adobe Acrobat/Acrobat Reader restrict the NRG Form from connecting to EMA's Web Services. To address this issue, the following actions can be taken:

1. When opening the form for the first time: a banner appears indicating 'Some features have been disabled to avoid potential security risks. Only enable these features if you trust this document'. Please click on the 'Options' button and select 'Trust this document always.'
2. If, after completing step 1, the drop-down lists/search fields still do not function: users are advised to follow specific instructions on 'how to allow access to a selected website' in Adobe Acrobat Reader/Adobe Acrobat.

   NOTE: You will be asked to add the website address in the Host name text box, please type: http://spor.ema.europa.eu/rmswi/#/

3. If following steps 1 and/or 2 has not led to successfully amending the security settings: users are recommended to contact their local IT service desk and request that they allow the form access to the following URLs:
   https://spor.ema.europa.eu/rmswi/#/lists/100000000002/terms ;
   https://spor.ema.europa.eu/rmswi/#/lists/100000073345/terms ;
   https://spor.ema.europa.eu/rmswi/#/lists/200000000004/terms

   NOTE: Without granting access to this location, the NRG Form **cannot** be fully completed.

3.3. Design/formatting limitations - Rev. Dec 2025

Q.6. Is it possible to track changes within the electronic form?

This functionality is not currently available in the interactive Acrobat forms.

Q.7. What to do if the information I am trying to include cannot be added due to limitations of the NRG Form's design and formatting?

A word count limit applies to certain sections of the form (e.g. 'Detailed grounds for rejection' section within the justification form). If that is the case, please include a summary that addresses all relevant points (e.g. in justification forms, please make sure to describe grounds for rejection for all identified name similarities).

If you feel that important information cannot be included in the form because of its design/format, please contact the NRG secretariat at NRG@ema.europa.eu.

3.4. Section-specific guidance - NEW Dec 2025

Instructions are given below on how to complete specific sections of the form where questions frequently arise.

REQUEST FORM
Proposed (Invented) Name(s)

This form should be read in conjunction with the 'Guideline on the Acceptability of Names for Human Medicinal Products Processed through the Centralised Procedure' (CHMP/287710/2014)

3.4.1. Form Type

Form Type	Form Type? ◉ Request Form	○ Justification Form

Q.8. When should I select 'Request Form' or 'Justification Form'?

- Select **'Request Form'** if you are submitting a new name review request, a request for reconfirmation, a request for re-use, or a request to change an accepted (invented) name.
- Select **'Justification Form'** if you are providing a justification for retaining a name that was previously rejected by the NRG.

Q.9. I would like to withdraw a name already accepted by the NRG. Should I complete/submit an NRG Form to formalise the request?

No. To notify your intent to withdraw a name, please send an email to NRG@ema.europa.eu.

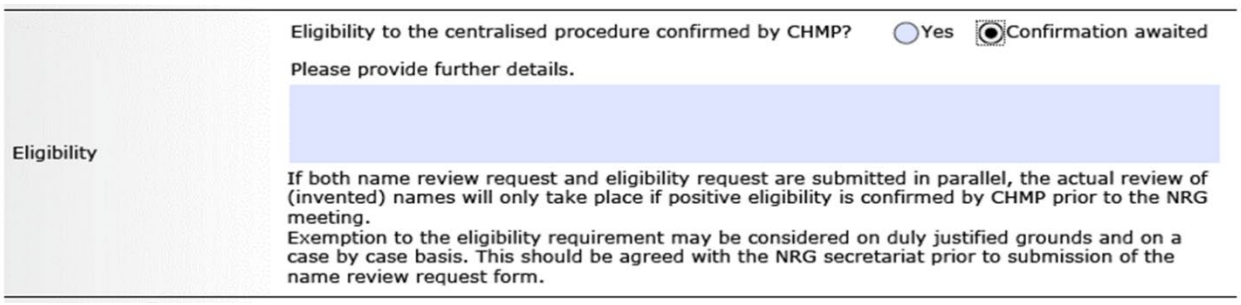
Please note that it is not permitted to withdraw an (invented) name solely to allow review of new names. Applicants must explain the rationale behind the withdrawal and provide relevant supporting documentation. For example, if the withdrawal is due to constraints in achieving a global name, applicants must submit documentary evidence from the relevant regulatory authority (e.g. official notification, outcome letter, etc.). For more details on acceptable grounds for withdrawal and subsequent review of additional proposed (invented) names under the same application, see section 6.1 of the *Guideline on the acceptability of names for human medicinal products processed through the centralised procedure*.

3.4.2. Eligibility

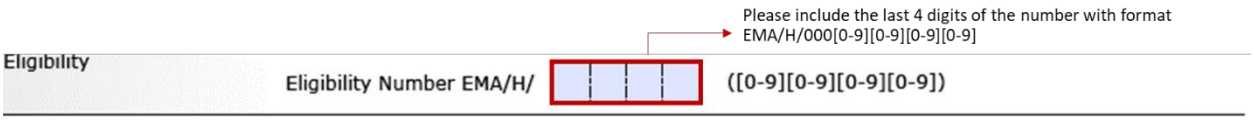
Q.10. Can name review requests be submitted in parallel with the eligibility request for centralised marketing authorisation?

Yes. However, proposed (invented) names can only be reviewed by the NRG if positive eligibility has been granted by the CHMP **before** the target NRG plenary meeting.

If, at the time of submitting the NRG Form, your Marketing Authorisation Application (MAA) has not yet been assigned an eligibility number in the format EMA/H/000[0-9][0-9][0-9][0-9], select the option **'Confirmation awaited'**. Additionally, please provide details on the date the eligibility request was submitted and the expected CHMP confirmation date. Once an eligibility number is assigned and eligibility is confirmed, inform the NRG secretariat at NRG@ema.europa.eu

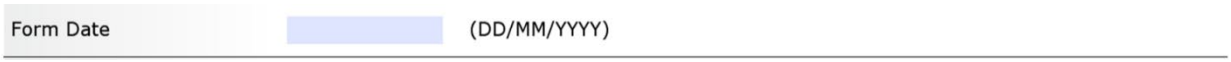


If, at the time of submitting the NRG Form, your MAA has been assigned an eligibility number, select the option **'Yes'** and complete accordingly.

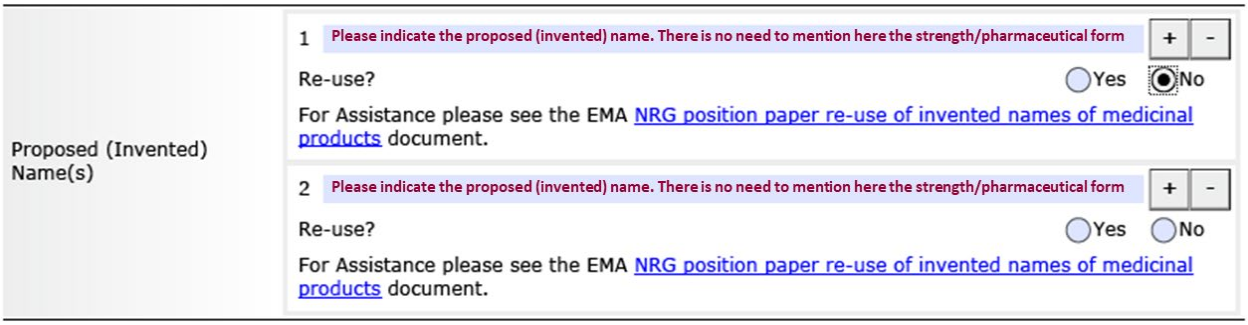


3.4.3. Form date

Please include the submission date to the NRG secretariat.



3.4.4. Proposed (invented) name(s)



IMPORTANT: Do not insert additional spaces or line breaks (e.g. pressing *Enter*) after the proposed (invented) name. This may cause formatting inconsistencies and lead to processing issues during the review of your application.

Q.11. Is the number of (invented) names reviewed by the NRG per MAA limited?

Yes. In principle, once two proposed (invented) names have been accepted by the NRG for a MAA, new requests for additional names under the same eligibility number will not be allowed. Therefore, a maximum of **two (invented) names per eligibility number** can be included in the NRG Form and proposed for review at each NRG plenary meeting. This limit also applies to different strengths and/or pharmaceutical forms evaluated under the same MAA.

Q.12. Do names presented under the construction 'INN + company name/trade mark' need to be reviewed by the NRG?

Yes. Names presented under the construction 'INN + company name/trade mark' must also be submitted for review by the NRG.

Q.13. Can I include within the same NRG Form name review requests for products with different eligibility numbers?

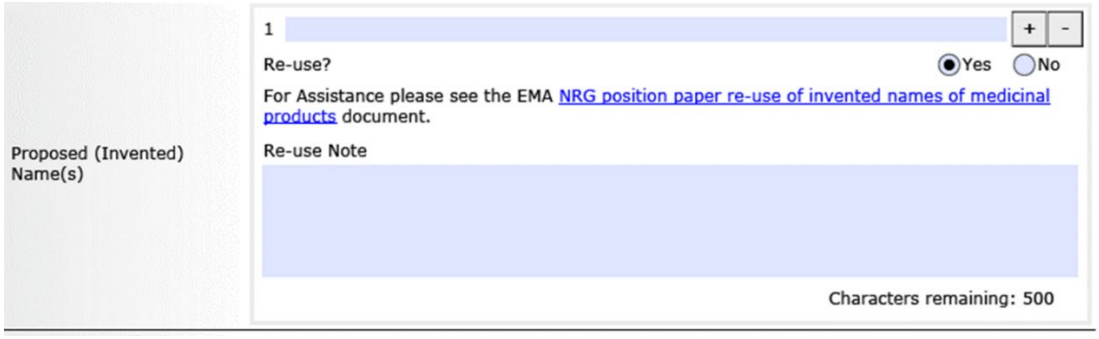
No. Each form must contain requests specific to a **single product profile** (i.e. **eligibility number**). Therefore, name review requests for duplicate MAAs must be submitted in **separate forms**.

Q.14. I plan to submit a new name request and a justification request for the same product profile (i.e. same eligibility number). Can I include both requests in the same form?

No. In this case, applicants must complete two separate forms: one request form and one justification form. Additionally, only **one NRG Form should be submitted per Eudralink message or email**; a name request form and a justification form for the same product must be submitted separately.

Q.15. Is it required to justify the re-use of an (invented) name?

Yes. Please include relevant explanations in the 'Re-use Note' box. It is important to clarify whether the (invented) name has already been used in a previous MAA, and whether the product has been authorised and marketed under that name.

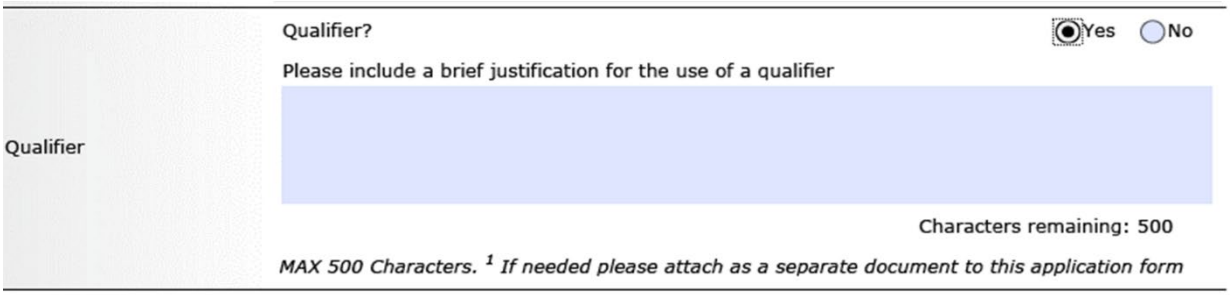


When reviewing re-use requests, the NRG considers aspects related to product awareness (e.g. safety issues, industry communications, public documents from health authorities, healthcare professionals, patient organisations, etc.), as well as the potential risk of mix-up. Applicants are advised to provide supportive documentation to address these concerns.

3.4.5. Qualifiers

Q.16. Is it necessary to justify the use of a qualifier?

Yes. Applicants must provide a justification for the use of a qualifier and its proposed format (i.e. by letters, numbers or a combination of both). For detailed guidance on the use of qualifiers, see section 4.1.13 of the *Guideline on the acceptability of names for human medicinal products processed through the centralised procedure.*



3.4.6. Reconfirmation

Q.17. When is it appropriate to submit a request for reconfirmation?

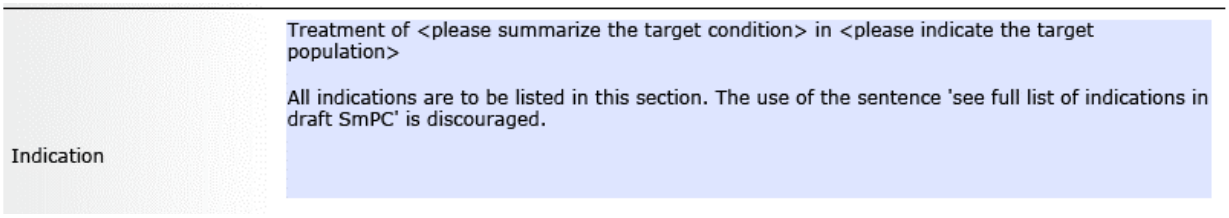
Requests for reconfirmation (i.e. a one-year validity extension) apply only to **accepted (invented) names with the same product profile (i.e. same eligibility number) that are still valid**. A reconfirmation can be granted **only once**, and must be requested before the name expires.

Q.18. What timeframe should I consider when submitting a request for reconfirmation?

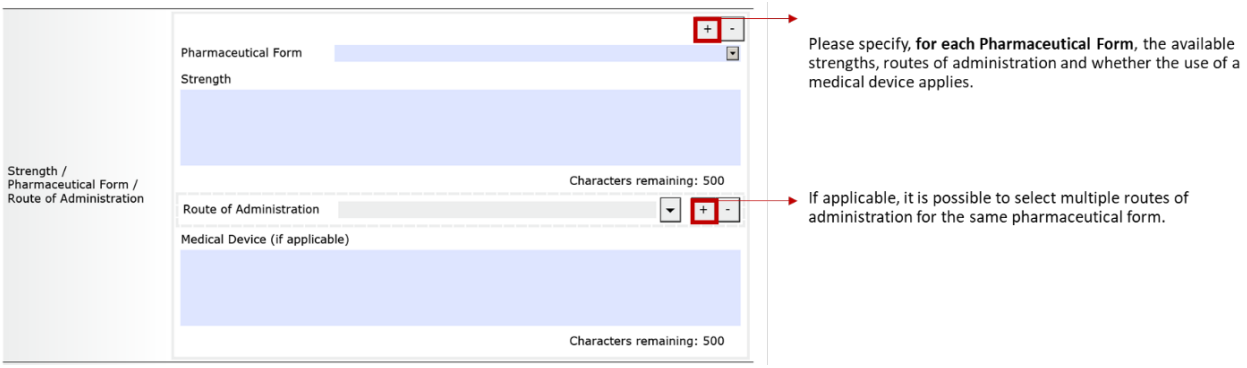
Requests for reconfirmation should be submitted sufficiently in advance to ensure review by the NRG **before the name expires.** For the full list of NRG meeting dates and submission deadlines, see Pre-authorisation guidance>Q&A: 3.1 Product name, product information and prescription status>3.1.2

Applicants are responsible for monitoring the validity of accepted names. To determine the expiry date, use the CHMP decision date when the name was first accepted as the reference point.

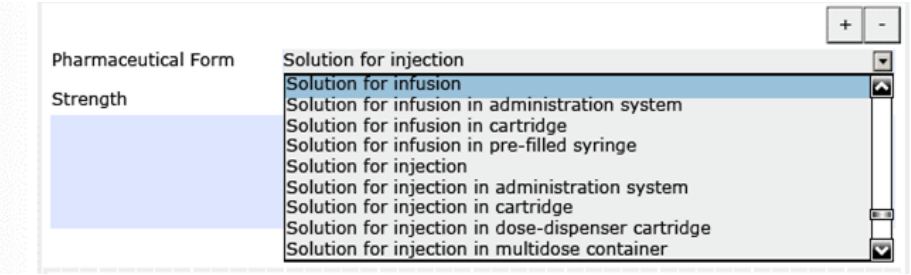
3.4.7. Indication



3.4.8. Strength/ Pharmaceutical Form/ Route of Administration

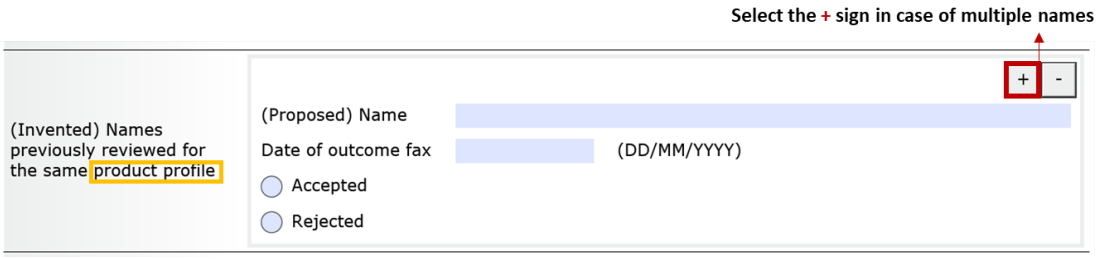


The **pharmaceutical form** is to be selected from a drop-down menu. Please be aware that several options start with the same term (see example below). Please select the option that applies, as proposed in the draft SmPC.



To express the **strength**, please refer to the *SmPC guideline* and the *QRD recommendations on the expression of strength in the name of centrally authorised human medicinal products*.

3.4.9. (Invented) names previously reviewed for the same product profile



IMPORTANT: It is mandatory to indicate all (invented) names that have been reviewed for the same product profile (**i.e. same eligibility number**).

If this section is not applicable, please leave it blank. **Do not** type "not applicable" or "N/A".

A proposed (invented) name may have been rejected and later accepted by the NRG, or vice versa. If that is the case, please refer to the latest outcome fax received and to the most updated status of the name.

3.4.10. Other relevant information

Q.19. What type of information should I include under 'Other relevant information'?

This section should be used to provide details such as:

1. **Results of the name safety research** conducted for the proposed (invented) names, including any assessment of potential risks to patients in case of mix-up, and the **list of similar product names identified**.
2. **Order of preference** for retaining the proposed (invented) names.

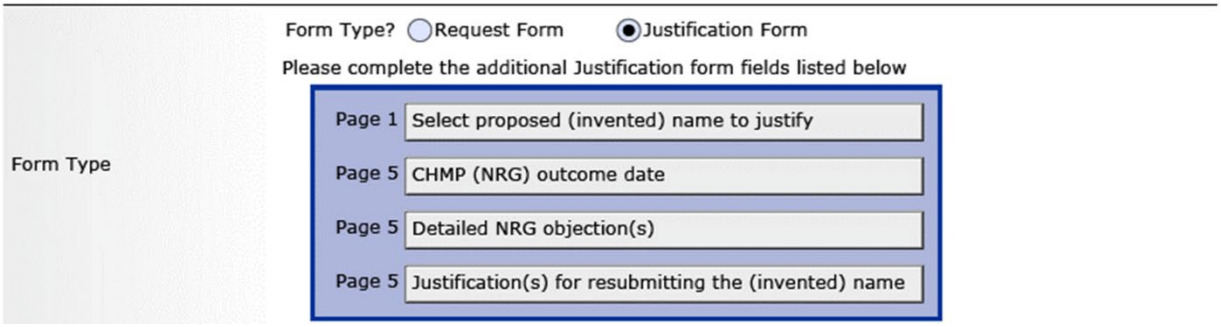
The NRG reviews proposed (invented) names in the preference order indicated by the applicant/MAH. When the limit of two accepted (invented) names is reached within a meeting, the NRG will refer to the submitted order of preference for retention of names and will stop the review of any subsequent proposals. Applicants are strongly recommended to take notice of this practice and indicate the order of preference in advance of the NRG meeting. This information can be included under 'Other relevant information'.

3.4.11. Applicant and contact person details

It is important to **indicate whether the applicant in charge of the submission is different from the MAH.** If that is the case, please select 'Yes'. Under the section titled 'On behalf of', please include all relevant information concerning the MAH.

3.4.12. Information specific to the Justification Form

As listed in the image below, additional form fields need to be completed when submitting a justification request.



When submitting a justification request, applicants should note the following:

1. Only one proposed (invented) name can be included per justification form.
2. The section 'Justification(s) for resubmitting the (invented) name' within the form must be completed, even if a full justification report is attached. Please include a summary of the key outcomes from the justification report in this section. This is essential to facilitate accurate data entry into the NRG agenda.
3. A word count limit applies to the sections 'Detailed NRG objections(s)' and 'Justification(s) for resubmitting the (invented) name'. Please provide a concise summary that addresses all relevant points (e.g. describe the grounds for rejection for all identified name similarities).

4. Saving and submitting the NRG Form

4.1. Saving data from the NRG Form - Rev. Dec 2025

Q.20. Can I save the NRG Form and come back to it later if I haven't finished completing it?

Yes. To save the form, press Ctrl + S or click the Save Form button located on the last page of the document. Progress will be saved as an Adobe PDF file in the download location. Note that if you have not saved it to a specific location, this action opens the 'Save As' dialogue to prompt saving in a particular folder other than the default location. Make a note of where the document is saved to easily pick up where you left off.

Q.21. How will the XML contained within the NRG Form be used?

When you save the PDF, the XML (eXtensible Mark-up Language) is also saved as a part of the file. It is possible to extract and view the XML and to store the file for use later. The intention is to allow the data from within the form to be more efficiently extracted and automatically uploaded to NRG database backend.

4.2. Export and import XML functionality

Q.22. What is the 'Export XML' function for?

The 'Export XML' function allows users to extract the content of the electronic form in the XML file format. This is useful in a number of ways, including:

1. The XML output can be used in other IT systems.
2. Previously exported XML outputs may be imported into a new version of the form, as long as the underlying .xsd (XML Schema Definition) has not changed in the interim.
3. The XML file is much smaller than the PDF file so may be considered more suitable for archiving.

IMPORTANT: The NRG Form must **NOT** be submitted to the NRG secretariat as an XML file. **Always submit the form as an Adobe PDF file.**

Q.23. Can I export the XML contained within the NRG Form?

Yes. It is possible to extract and view the XML. See instructions below:

1. Navigate to the last page in the PDF, then click Export XML to export an XML file.
2. To export the full form XML (including the drop-down list cache in the envelope node of the schema), click 'No' when asked 'Would you like to export just the user entered form data?'.
3. To extract the user entered data only, click 'Yes' when asked 'Would you like to export just the user entered form data?'.
4. Save the file in your local file system and use your chosen XML file editor to view the data and its structure.

NOTE: You may also use the inbuilt export XML tool in Reader or Acrobat. The procedure to reach the inbuilt function varies in the different major software versions. The common procedure paths are listed below:

Acrobat 8: File>Export>XML 1.0

Acrobat 9: Forms>Manage Form Data>Export Data

Reader 10: Extended>Export Data

Q.24. Can I import previously completed XML data in the NRG Form?

Yes. It is possible to import XML data in the correct format, if you have previously exported XML data (as long as the underlying .xsd (XML Schema Definition) has not changed in the interim). See instructions below:

1. Navigate to the last page in the PDF, then click 

to open the file system browser to find a previously created XML file.
2. Once the XML is imported, save, close then re-open the form whilst online to refresh the lists.

NOTE: You may also use the inbuilt import XML in Reader or Acrobat to import previously completed form data.

IMPORTANT: Performing this procedure may overwrite the cached drop-down lists with an older version. To ensure this is remedied, save, close then re-open the form whilst online. This ensures the lists refresh, overwriting any out of date list content in the form cache.

4.3. Submitting the NRG Form - Rev. Dec 2025

Q.25. What are the submission dates for (invented) name requests?

A full list of NRG meeting dates and submission deadlines is available here: Pre-authorisation guidance>Q&A: 3.1 Product name, product information and prescription status>3.1.2

Applicants must comply with these deadlines to ensure their requests are reviewed at the next NRG meeting.

Q.26. Is there a requirement to deliver a signed paper copy of the electronic submission?

No. A signed paper copy is not required, as per existing process.

Q.27. How do I submit the electronic NRG form?

There are two valid submission methods: via Eudralink or by email to NRG@ema.europa.eu. Ensure all supporting documents are attached separately (not in folders or zip files).

Q.28. How do I apply for a Eudralink account?

To open a Eudralink account, submit a request via the EMA Service Desk portal. For technical support, visit the EMA Service Desk Portal or call +31 (0) 88781 6000 for urgent matters.

Q.29. What should I consider when setting the expiry date of a Eudralink package?

The expiry date should not be shorter than the duration of the name review process, which includes the date of formal adoption of the NRG conclusion by the CHMP.

List of acronyms

CHMP	Committee for Medicinal Products for Human Use
EC	European Commission
EU	European Union
INN	International non-proprietary name
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
NRG	Name Review Group
SmPC	Summary of product characteristics
XML	Extensible Mark-up Language