EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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NRG position paper re-use of invented names of medicinal products

1. Background

The invented name of a medicinal product should, as a matter of principle, not create any public-health concern or potential safety risk. The NRG is reviewing the acceptability of a proposed name based on criteria set out in the respective guideline (CPMP/328/98, Revision 5). An essential element of such review is to ensure that an invented name of a medicinal product is not causing confusion with the name of another medicinal product, since such confusion could lead to safety issues with respect to the use of these products.

Within this general context, the possibility for re-use of the same (identical) invented name has been raised to the NRG. Acknowledging the need for an assessment on a case-by-case basis this position paper intends to clarify the principle considerations for such assessment.

2. Scope

The aim of this position paper is to provide the criteria applied by the NRG in case a request for re-use of an invented name is received from an applicant.

3. Methodology

The re-use of an invented name might bear the potential risk of confusion for different medicines depending on the specific case. There is no legal reference for the re-use of invented names. Decisions are being taken on a case-by-case basis.

4. Principle considerations

The NRG reviews the acceptability of a proposed invented name for use with a specific product taking into account the product profile (as defined in the guideline CPMP/328/98, Revision 5). Product profile summarises all characteristics that define a specific product; this includes, but is not limited to, the following:

- *indication(s)*
- *active substance*
- *patient population(s)*
- *pharmaceutical form(s)*
- *strength(s)*
- *route(s) of administration*
- *setting for dispensing and use;*

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- legal status/classification for supply (i.e. medicinal products subject to medical prescription, medicinal products not subject to medical prescription, medicinal products subject to restricted and/or special medical prescription).
- Orphan (designation) status;
- New pharmaceutical forms and/or route of administration for the medicinal product concerned, as appropriate.

- Assessment of potential for harm to the patient in case of a mix-up (e.g. age group, excipients, adjuvant, origin, knowledge of off-label use).

An outcome of a name review, which indicates acceptability, is strictly related to the product profile presented by the applicant.

It should be noted that any review of a proposed name by the CHMP (NRG) and the conclusion about acceptability is based on the information available at the time of review. If acceptability is confirmed, this allows the applicant to use the name in an application for a central marketing authorisation. The current name review system allows applicants to request the review of several proposed invented names for one medicinal product even though only one of these may later be held for the marketing authorisation. This leads to a number of names that are accepted by the NRG and unused by applicants. It has been identified that this may cause difficulties in finding future acceptable names by applicants, particularly as details of the accepted and unused names cannot be disclosed for confidentiality reasons.

The NRG will therefore consider the acceptability of a newly requested name for 3 years, which will commence at the time of the final outcome of the initial assessment of the acceptability. The accepted name is considered to be in use once the initial marketing authorisation application (MAA) has been submitted. The initially granted 3 years of acceptance for an invented name can be extended once, for further 3 years upon request from the applicant. In exceptional cases and if duly justified by the applicant, a further extension might be accepted by the NRG. It will be the responsibility of the applicant to monitor the lapse of the acceptance period and to submit a written request for an extension, if applicable, at least 3 months before the expiry date. It is to be noted that maximum of 4 of the originally approved names can be eligible for an extension.

5. Criteria applied by the NRG when assessing the acceptability of re-using a previously accepted name

Several scenarios can be envisaged by the NRG in order to identify and consider the potential risks to public health that the re-use of an invented name may pose. It should be noted that when the applicant for a re-use of the name is different from the initial applicant, the applicant for the re-use should provide proof of the agreement with the initial applicant.

5.1. Re-use of an invented name that has previously been proposed for a product with the same product profile

If the product for which the previously accepted invented name should be re-used has the same product profile as the one for which this name was used, then the following scenarios can be foreseen:

5.1.1 Used in a MAA

- **MA not granted**
- **MA granted**
  - **a)** Marketed
    - Still active/ Suspended
    - Revoked / Withdrawn
  - **b)** Never marketed
    - Suspended
    - Revoked/ Withdrawn

5.1.2 Not used in a MA

5.1.1. Used in a MAA

- **MA not granted**

If the invented name intended for re-use was already used in an application but a marketing authorisation (MA) has not been granted (e.g. a negative opinion was adopted by the CHMP), the applicant may wish to re-submit their consolidated MAA to the CHMP and re-use the same invented name that was previously acceptable by the NRG taking into account the conditions mentioned in section IV.

- **MA granted**

If the invented name has already been used in an application which was finalised with a positive opinion from the CHMP, a marketing authorisation was granted using the invented name.

a) Marketed

In case the MA was followed by placing the product on the market, the MA is still active at time of intended re-use, but the initial name has been changed in the meantime, such re-use of the original name for a different Marketing Authorisation with the same product profile is unlikely to cause any risk for public health concerns. Examples are multiple applications, where the name of the initial MA is changed after authorisation. In principle, the same applies for a suspended MA.

If the product was marketed, but the MA was subsequently revoked/withdrawn and the MAH wishes to re-use the same invented name when re-applying for a new MA, this would require a case-by-case decision taking into consideration the reasons for the revocation/withdrawal. If the reason was safety related, then it might be inappropriate to re-use the same name unless the established awareness might be considered supportive for the appropriate future use of the product. The applicant should re-apply for the use of the same name to the NRG.

b) Never marketed

If a marketing authorisation was granted using an invented name, but this was not followed by placing of the product on the market, the following situations can be foreseen:

If the MA was suspended, the suspension can be lifted and the product may be introduced to the market. Therefore, the re-use of names can only be envisaged as a transfer to another MA which concerns the same product profile (as for example in case of Informed Consent Applications, or a line extension as a separate MA, bearing the same name).

If the MA was subsequently revoked/withdrawn and the MAH wishes to re-use the same invented name when re-applying for a new MA, this would require a case-by-case decision taking into consideration the reasons for the revocation/withdrawal. If the reason was related to safety, it might be inappropriate to use the same name later again unless the awareness might be considered supportive for the appropriate future use of the product. The applicant should reconfirm the use of the name with the NRG.

5.1.2. Not used in a MAA

If the invented name has not been used in an application yet, the applicant may use the invented name for the same product profile taking into account the conditions mentioned in section IV.

5.2. Re-use of an invented name that has previously been proposed for a product with a different product profile

If the product for which the previously accepted invented name should be re-used has a different product profile than the one for which this name was used, then the following scenarios can be foreseen:

5.2.1 Used in a MAA

- **MA not granted**
- **MA granted**
  - **a)** Marketed
    - Still active/ Suspended
    - Revoked / Withdrawn
  - **b)** Never marketed
    - Suspended
    - Revoked/ Withdrawn

5.2.2 Not used in a MAA

5.2.1 Used in a MAA

- **MA not granted**

If the invented name intended for re-use was already used in an application for a different product profile but a MA was not granted (e.g. a negative opinion was adopted by the CHMP), this may have resulted in the release of numerous documents to the public containing information regarding the negative opinion, including the proposed invented name, hence creating public awareness. In addition to the official communication issued by the Regulatory Bodies, the product awareness created among the different interested fora (e.g. healthcare professionals, patient organisations) must be taken into consideration when considering a potential name re-use for a different product profile.

Based on these grounds, the re-use of an invented name for a different product profile seems possible only in exceptional circumstances. Evaluation will be carried out on a case-by-case basis and name re-use can only be accepted if no safety issues are identified.

- **MA granted**

a) Marketed

If the invented name intended for re-use was already applied for in an earlier MAA for a certain product profile, received a positive CHMP opinion and the MA was issued using this invented name, it is very unlikely that the same name can later be re-used for a product with a different product profile. This would be based on public health concerns and/or potential safety risks as a result of the likely product mix-up. The NRG would consider whether any public use of the invented name would be likely to provoke confusion and safety concerns in relation to a new MA. Applicants may wish to provide supportive documentation to alleviate concerns around public awareness.

The re-use of such name is unlikely to be acceptable as the original product has been placed on the market and made available to the healthcare professionals/patients. This is irrespective of the current status of the initial MA.

b) Never marketed

If a marketing authorisation for a different product profile was granted using the invented name intended for re-use, but this was not followed by a placement of the product on the market, the product was not effectively available. Thus, there might be some rare situations where the name re-use could be acceptable, following the approval of the NRG.

If the MA was suspended, the suspension can be lifted and the product may be introduced to the market. Therefore, the re-use of the invented name is not acceptable.

If the MA was revoked/withdrawn and the MAH wishes to re-use the same invented name when applying for a new MA for a different product profile, this requires a case-by-case decision taking into consideration the reasons for the revocation/withdrawal. It might be considered inappropriate to re-use the same name, especially if the reason for revocation/withdrawal was safety related. Product awareness could have been created via public communications of Regulatory Bodies, of interested parties, company communications, etc. The applicant must take into account the potential negative connotation associated with the invented name as a result of the negative publicity caused by the revocation/ withdrawal of the MA and that this does not raise any safety concerns. The name re-use might therefore be possible only in exceptional circumstances. The applicant should reconfirm the use of the name with the NRG.

5.2.2 Not used in a MAA

If the invented name has not been yet used in an application, and the applicant wishes to use the previously reviewed name for a different product profile, a complete new assessment will be performed by the NRG as the acceptance is strictly linked to the product profile (see IV). As the product profile plays an essential role in the assessment performed by the NRG, different objections might be identified.

6. Conclusions

The re-use of the invented name of a medicinal product requires careful consideration in each individual case.

Invented names accepted by the NRG will remain available for use by the applicant for 3 years. If more than 3 years have elapsed since the NRG opinion, the applicant must seek reconfirmation from the NRG for the re-use of the name at least 3 months before the expiry even if it is to be used for the same product profile. Provided that no objections are endorsed, the re-use of the same invented name which was previously deemed acceptable for the same or a different product profile, could still be considered acceptable by the NRG.

The acceptability of a name is strictly linked to a product profile. If a name was used in an MA application, then the re-use of this name for the same product profile might be possible whereas its re-use for a different product profile would be inappropriate in most circumstances. However, it will need to be considered whether the initial MA was granted and whether the product was placed on the market.

Evaluation needs to be carried out on a case-by-case basis and in line with the general principles for the name review. The re-use would only be deemed acceptable provided that the risks to public heath do not outweigh the benefit of facilitating the access of the medicinal product to the market.