Human Medicines - EMEA Pre-Submission Procedural Advice

How will I know if the proposed invented name of my medicinal product is acceptable from a public health point of view?

In accordance with Article 6 of Regulation (EC) No 726/2004, "each application for the authorisation of a medicinal product for human use (…), 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." The Centralised Procedure therefore requires one single name for the medicinal product to be authorised.

According to Article 1(20) of Directive 2001/83/EC, as amended, the name of the medicinal product "may be either an **invented name** not liable to confusion with the common name, or a **common name** or **scientific name** accompanied by a trademark or the name of the Marketing Authorisation Holder". It is also understood by legislation that a common name is according to Article 1(21) of Directive 2001/83/EC, as amended, "*The international non-proprietary name* (INN) recommended by the World Health Organisation, or, if one does not exist, the *usual common name*".

Although it is not mandatory under Community legislation, in practice, many companies submitting marketing authorisation applications under the Centralised Procedure wish to use invented names for their medicinal products.

As part of the EMEA's role in evaluating the safety of medicinal products in the centralised marketing authorisation procedure, it is obliged to consider whether the invented name proposed for a medicinal product could create a public-health concern or potential safety risks.

In particular, the invented name of a medicinal product:

- should not be liable to cause confusion in print, handwriting or speech with the invented name of an existing medicinal product
- should not convey misleading therapeutic or pharmaceutical connotations
- should not be misleading with respect to the composition of the product

Further concerns may relate to similarities with or inclusion of INNs/INN stems, as well as other public health concerns. Product specific concerns, like for non-prescription medicinal products or generic/hybrid/similar biological medicinal products, are being addressed as appropriate.

In order to identify, at an early stage, potential difficulties presented by the invented name(s) proposed by an applicant, the EMEA/CHMP set up a group, the Name Review Group (NRG), to perform reviews of proposed names from a safety/public health point of view. The NRG is also responsible for updating the "Guideline on the acceptability of names for human medicinal products processed through the centralised procedure"(CPMP/328/98).

The (Invented) Name Review Group (NRG)

The NRG is composed of representatives from EU Member States and is chaired by an EMEA representative. Representatives of the European Commission and the EMEA Secretariat also participate in the work of the group. Other relevant experts (e.g. WHO experts) are consulted on a case-by-case basis.

The NRG meets on a regular basis. Its conclusions are presented for adoption at the following plenary CHMP meeting.

The criteria applied by the NRG when reviewing the acceptability of proposed names are detailed in the "Guideline on the acceptability of names for human medicinal products processed through the centralised procedure"(CPMP/328/98), hereafter referred to as the 'Guideline'.

EMEA procedure for checking proposed invented names

- Submission of the invented name request by the Applicant/MAH

Provided that the medicinal product is eligible for evaluation under the Centralised Procedure, the applicant should inform the EMEA of the proposed invented name(s) for their medicinal product at the earliest 18 months prior to the planned submission date of the marketing authorisation application. See also the deadlines for submission of Proposed Invented Names.

The 'Proposed Invented Name Request form', along with either a draft Summary of Product Characteristics (SPC) or a product profile (including details about the mode of action, therapeutic indication, posology, route of administration and legal status, as well as other information considered relevant), should be sent to the EMEA at the e-mail address: NRG@emea.europa.eu.

The applicant may propose up to four invented names per marketing authorisation application indicating its preference, if any, so that the acceptability of a 'back-up' invented name can be considered without loss of time.
Applicants should follow the criteria described in the 'Guideline' when proposing invented names.

Where the applicant submits proposed invented names intended to be used in the context of multiple marketing authorisations/applications it shall specifically request the NRG to consider whether the proposed invented names cannot be considered potentially confusing with each other (see also question on Multiple Applications).

- Consultation with the Member States and WHO and NRG discussion/CHMP adoption

The proposed invented name(s) and all the background information provided by the applicant(s)/MAH(s) are sent to every NRG contact point nominated by National Competent Authorities (NCAs) of EU Member States, the European Commission (EC) and the World Health Organisation (WHO) for their review and will subsequently be discussed at the NRG meeting. The detailed procedure is described in the 'Guideline'.

The NRG conclusions/recommendations are presented for adoption to the following CHMP plenary meeting, after which the applicant will be informed of the outcome of the discussion on the acceptability of the proposed invented name(s) for their medicinal product together with the reasons and source for the objections(s) raised, where applicable. See also the dates of NRG discussion.

- Rejection by NRG/CHMP of a proposed invented name

In case of rejection of a proposed invented name by NRG/CHMP, the applicant/MAH has got the following possibilities:

1. To submit new invented names proposals, which are checked through the same procedure as described above.
2. To provide a justification to retain the invented name (addressing specifically all the objections raised) using the 'Invented Name Justification Form'. Such justification will be reviewed as described in the 'Guideline'.

If the proposed invented name cannot be accepted prior to submission, the Marketing authorisation application can be submitted under either any of the proposed invented names or the common name or scientific name accompanied by a trademark or the name of the MAH. At the latest one month prior to the adoption of the CHMP opinion on the concerned MAA, the applicant will in such case have to inform the EMEA (PTL) and the NRG Secretariat on the acceptable invented name of their choice.

In the event no invented name is accepted prior to adoption of the CHMP opinion, the Applicant will obtain its medicinal product opinion adopted under the common name or scientific name accompanied by the name of the MAH. In such a case, as soon as the Commission Decision is granted, the MAH may submit a variation to introduce an invented name, on the condition that such name has been considered acceptable by the NRG.

Exceptionally, provided *all means have been exhausted*, the applicant/MAH may request the matter to be presented to the CHMP within the context of the evaluation of the medicinal product (e.g. oral explanation).

- Change of the invented name after the marketing authorisation is granted

In accordance with Commission Regulation (EC) No 1085/2003 as amended, the (invented) name of a medicinal product may be changed after a marketing authorisation is granted through a Type IB (No.2) variation procedure.
Such variation application should be submitted in accordance with the procedure described in Article 5 of Commission Regulation (EC) No 1085/2003, for Type IB variations and the conditions described in the Annex I to the same Regulation (see also EMEA post-authorisation guidance).
Taking into account that the MAH will be required to submit the EMEA letter of acceptance of the concerned invented as part of the variation application, it is recommended that the proposed invented name be submitted at least 4 months in advance of the intended Type IB (No.2) variation application, also taking the dates of NRG discussion into consideration.

References

- Regulation (EC) No 726/2004
- Directive 2001/83/EC, as amended
- "Centralised Procedure", the Rules governing Medicinal Products in the European Community, Notice to Applicants, Volume 2A, Chapter 4
- "Guideline on the acceptability of names for human medicinal products processed through the centralised procedure"(CPMP/328/98)
- Regulation (EC) No 1085/2003