Veterinary Medicines - EMEA Pre-Submission Guidance

Procedure for checking acceptability of (invented) names

The granting of a single Community marketing authorisation under the Centralised Procedure requires one single name for the medicinal product being authorised. In accordance with Community Legislation the name given to a medicinal product may be either (a) an invented name not liable to confusion with the common name or b) a common name or scientific name accompanied by a trademark or the name of the marketing authorisation holder.

Although it is not mandatory under EU legislation for the name of a medicinal product to be an invented name, in practice, companies submitting marketing authorisation applications under Community systems wish to use invented names for their products. The Centralised Procedure requires one single invented name for the medicinal product to be authorised. However, in exceptional cases, in particular where the proposed invented name has been cancelled, opposed or objected to under trade name law in a Member State, the Commission will address the issue in order not to disadvantage patients and their access to the concerned medicinal product in that Member State. If sufficient evidence is given by the Marketing Authorisation Holder that, in spite of all its efforts, the chosen or foreseen trade name cannot be used in a Member State, the Commission will - exceptionally- authorise the use of a different invented name in that Member State. Should a derogation be granted, it will affect neither the legal obligations of the Marketing Authorisation Holder, nor the validity of the marketing authorisation throughout the Community and shall not be used to introduce any partitioning of the European market, i.e. to restrict or prevent the free movement of the concerned medicinal product.

As part of the EMEA's role in evaluating the safety of medicinal products in the authorisation procedure, it is obliged to consider whether the proposed invented name of a medicinal product could create a risk to public and animal health. It is evident that even where an invented name has been registered for a medicinal product, public health considerations must determine whether that invented name may be used for a veterinary medicinal product. In particular the EMEA is obliged to ensure that a product should not bear an invented name, which could be confused with that borne by another product.

In order to enable applicants to propose invented names which will be acceptable from a public and animal health perspective, it is crucial that:

- a transparent procedure for checking the acceptability of proposed invented names is operated;
- consistent, non-arbitrary criteria are applied when reviewing the acceptability of proposed names;
- objections to proposed invented names are forwarded to the EMEA within 30 days of notification of such names. Further, the basis for objection should be explained clearly and in sufficient detail for the applicant to fully understand the basis for the objection.

The difficulties that have typically been encountered with product invented names arising from such public and animal health concerns are outlined below. Additionally, the procedure operated by the

EMEA in liaison with the CVMP and Member States in order to ensure that objections are identified at an early point is also described.

Public health concerns and invented names:

In view of the experience accumulated to date under the Centralised Procedure, certain features of proposed invented names, which tend to give rise to concerns, can be identified. These features are summarised below.

- The invented name of a medicinal product should not convey misleading therapeutic or pharmaceutical connotations.
- The invented name of a veterinary medicinal product should not be misleading with respect to the composition of the product.
- The invented name of a veterinary medicinal product should not be liable to cause confusion in print, handwriting or speech with the invented name of an existing veterinary medicinal product.
- The invented name of a product should avoid qualification by letters where possible.
- The use of short qualifications/abbreviations which do not carry an established and relevant meaning in all Member States is unacceptable.
- The invented name should comply with WHO Guidance e.g., it would be appreciated if invented names were not derived from international non-proprietary names (INNs) and if INN stems were not used in invented names.

Finally, it should be highlighted that the issue of whether a particular invented name will or may constitute an infringement of another entity's invented name rights cannot be one of the EMEA's concerns and is therefore not taken into account by the EMEA in its consideration of the acceptability of a proposed invented name.

EMEA procedure for identifying difficulties with invented names:

Given the role of the EMEA in the Centralised Procedure, it is well placed to identify, at an early stage, potential difficulties presented by the invented name(s) proposed by an applicant. In order to minimise any problems created by the objections of National Competent Authorities in relation to the use of an invented name on grounds relating to the protection of public and animal health, the EMEA operates a procedure to ensure that such objections are identified at an early point.

Under this procedure when an applicant notifies the EMEA of an intention to submit an application (i.e. at the latest 4-6 months prior to planned submission date), the applicant should inform the EMEA of the proposed invented name for his product. More than one invented name can be proposed for consideration and the applicant can indicate his preference, so that the acceptability of any back-up invented name can be considered without loss of time. Applicants must in all cases submit electronically the invented name application form(s) with all the detailed information requested, concerning the invented name(s) to be considered.

National Competent Authorities are contacted by the EMEA and asked to consider the proposed invented name(s). The request to consider the proposed invented name can even be made at an earlier stage. The National Competent Authorities are requested to inform the EMEA about any objections to the proposed invented name(s) on grounds of public health risk within 30 days of receipt of such notification.

The proposed invented name and any objections to the proposed invented name(s) together with the nature of the public health risk involved are then discussed at the next CVMP meeting. Immediately after the CVMP meeting the applicant is informed of the outcome of the discussion.

In the event that there are objections to the proposed invented name(s), the applicant is invited to justify retention of such invented name and to provide arguments countering the public health risk identified or to propose an alternative invented name:

- This invented name will be similarly put to the CVMP for consideration in accordance with the procedure described above.
- If a justification is provided (using the appropriate form) it will be discussed at the next CVMP meeting and the applicant will be immediately informed of the outcome. If the justification is not accepted, an alternative invented name should be proposed.

If the invented name issue cannot be resolved prior to submission, the application can be submitted using the common name together with a trademark or the trade name of the manufacturer. In all cases, the applicant should propose any alternative invented name at the latest one month before the adoption of the CVMP Opinion (since the procedure described above involving the National Competent Authorities has to take place before adoption of the Opinion by the CVMP).

The practical experience of the EMEA to date has shown that this early intervention has permitted marketing authorisations to be granted without incurring delays related to invented name issues.

References

- The rules governing medicinal products in the European Union, Volume 6A, Notice to Applicants
- "Guideline on the acceptability of invented names for veterinary medicinal products processed through the centralised procedure"(CVMP/328/98 - Rev. 3)
- Commission Communication on the Community Marketing Authorisation procedures for medicinal products, OJ C 229/4 of 22 July 1998