



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 May 2013
EMA/248010/2007
Committee for Veterinary Medicinal Products (CVMP)
EMA/328/1998-Rev.3¹

Guideline on the acceptability of names for veterinary medicinal products processed through the centralised procedure

Adopted by CVMP for release for consultation	June 2007 ²
End of consultation (deadline for comments)	30 September 2007 ³
Adopted by CVMP	16 January 2008

The objective of the guideline is to provide applicants/Marketing Authorisation Holders (MAHs) guidance on the criteria applied by CVMP when reviewing the acceptability of the proposed names for medicinal products processed through the centralised procedure.

It provides details on the procedure for checking the acceptability of the proposed names.

¹ Formatting updates and new contact details

² Last day of relevant Committee meeting.

³ Last day of the month concerned.



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Executive summary

1. Introduction (background)

A Community marketing authorisation is valid throughout the European Union and the invented name of the medicinal product is an integral part of the authorisation. In accordance with Article 31(1) of Regulation (EC) No 726/2004, *“each application for the authorisation of a medicinal product for veterinary use (...), otherwise than in exceptional cases relating to the application of the law on trademarks, shall include the use of a single name for the medicinal product.”*

The centralised procedure therefore requires one single invented name for the medicinal product to be authorised. However, in exceptional cases, where the proposed trade mark has been cancelled, opposed or objected to under trade mark law in a Member State, the Commission may accept the existence of more than one name for a single product, in order not to disadvantage access to the concerned medicinal product in that Member State. To obtain such derogation, the Marketing Authorisation Holder shall provide enough evidence of its failed efforts. Should derogation be granted, it will not affect the legal obligations 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 concerned medicinal product. It is reminded that the MAH/Applicant must liaise directly with the European Commission to obtain derogation in writing.

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.

According to Article 1(22) of Directive 2001/82/EC, as amended, it should be noted that 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 trade mark or the name of the marketing authorisation holder”*. It is also understood by legislation that a **common name** is, according to Article 1(23) of Directive 2001/82/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”*.

As part of the European Medicines Agency's (the Agency) role in evaluating the safety of medicinal products in the authorisation procedure, it is obliged to consider whether the invented name proposed for a medicinal product could create an animal-health concern or potential safety risk.

It is evident that even where an invented name has been registered in Member States/ Community for a medicinal product, safety considerations must determine whether that invented name may be used for the medicinal product. In particular the Agency seeks to ensure that a medicinal product should not bear an invented name potentially to be confused with that borne by another medicinal product, since such confusion could raise safety issues with respect to the use of these products. It should be highlighted that the issue of whether a particular invented name will or may constitute an infringement of another entity's intellectual property rights cannot be one of the Agency's concerns and is therefore not taken into account by the Agency in its consideration of the acceptability of a proposed invented name.

Furthermore, the review of trademarks is not under the Agency remit since other authorities are responsible for such procedure, both at the national and the European level. The Applicant/MAH will have to contact these appropriate authorities directly to get such trademark registration.

All information sent by Applicants/MAHs in relation to invented names is considered confidential and all parties involved in the review of names within the centralised procedure, are bound by the Agency confidentiality policy and their own National or Authority rules of confidentiality.

2. Criteria applied when reviewing the acceptability of proposed invented names

When reviewing the acceptability of proposed invented names, the CVMP applies criteria based on animal health concerns, in particular with regard to safety, addressed in sections 2.1 to 2.4, respectively.

The Applicant/MAH would be expected to review the proposed invented name, applying the criteria outlined in this guideline, before requesting that an invented name(s) be considered. When appropriate, detailed information addressing the above should be provided within the invented name application form(s) or as part of a justification for retaining the invented name.

2.1. Addressing safety concerns in proposed invented names

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 (either a veterinary medicinal product or one for human use).

When assessing the potential for such confusion, the following aspects are considered systematically:

- The indication(s);
- Target species;
- Animal population(s);
- The pharmaceutical form(s);
- The route of administration(s);
- The strength(s);
- The setting for dispensing and use;
- The legal status/ classification for supply (i.e. medicinal product subject to medical prescription, medicinal product not subject to medical prescription, medicinal product subject to restricted or special medical prescription).
- (Potential) New pharmaceutical forms and/or routes of administration and/or target species for the medicinal product concerned as well as for the other medicinal products with a similar invented name, as appropriate.
- Assessment of potential for harm to the animal in case of a mix-up.

The invented name of a medicinal product should not convey misleading therapeutic and/or pharmaceutical connotations.

The invented name of a medicinal product should not be misleading with respect to the composition of the product.

2.2. Addressing international non-proprietary names' concerns in proposed invented names

According to Articles 1(22) and 1(23) of Directive 2001/82/EC, as amended, "... an invented name shall not be liable to confusion with the common name...". Furthermore when proposing an invented name, Applicant(s)/MAH(s) are advised to take into consideration WHO World Health Assembly resolution (WHA46.19), where appropriate i.e. "It would therefore be appreciated if invented names were not derived from international non-proprietary names (INNs) and if INN stems were not used in invented names".

Two types of INN concerns could be considered i.e. a potential similarity with a complete INN or the inclusion of an INN stem into the proposed invented name(s). Therefore:

2.2.1. Invented name is similar to an existing INN

Where a similarity between a proposed invented name and an existing INN is identified, the following criteria should be taken into consideration:

The closeness either in speech or in writing with its own or a different INN;

The similarity in medical setting, general use (indication(s) of concerned medicinal products;

The similarity in classification for supply of the concerned medicinal products

The target species, the route(s) of administration and, where possible the concerned pharmaceutical forms.

The Applicant/MAH would be expected to review INN similarity before requesting that the proposed invented name(s) be considered. When appropriate, detailed information addressing the above should be provided within the invented name application form(s) or as part of a justification for retaining the invented name.

The CVMP will take its decision on the acceptability of the proposed invented name according to the decision tree in Annex I.

INN related information is available on the WHO Web site:

<http://www.who.int/medicines/services/inn/innquidance/en/index.html>

<http://www.who.int/medicines/services/inn/GeneralprinciplesEn.pdf>

2.2.2. Invented name contains an existing INN stem

Where a proposed invented name includes an identified INN stem, the following criteria should be taken into consideration:

The similarity in therapeutic class between the 'INN stem' and the medicinal product;

The location of the 'INN stem' within the proposed invented name is as per WHO INN Stem location recommendations;

The similarity in medical setting, general use (indication) of concerned medicinal products;

The similarity in classification for supply of the concerned medicinal products.

The target species, the route(s) of administration and, where possible the concerned pharmaceutical forms.

The Applicant/MAH would be expected to review INN stem inclusion before requesting that the proposed invented name(s) be considered. When appropriate, detailed information addressing the above, should be provided within the invented name application form(s) or as part of a justification for retaining the invented name.

The CVMP will take its decision on the acceptability of the proposed invented name according to the decision tree in Annex I.

INN stems related information is available on the WHO Web site:

http://whqlibdoc.who.int/hq/2004/WHO_EDM_QSM_2004.5.pdf

<http://www.who.int/medicines/services/inn/GeneralprinciplesEn.pdf>

2.3. Addressing other public health concerns in proposed invented names

The invented name should preferably consist of one word only. The use of qualifiers/abbreviations by letters as part of the invented name should in principle be acceptable. The use of numbers may also in certain cases be acceptable, e.g. vaccines (see section 2.3). If qualifications/abbreviations are to be included, appropriate justification for their inclusion should be provided to the CVMP for consideration.

When assessing the acceptability of a proposed qualifier/abbreviation from an animal health point of view, the CVMP will take into consideration:

- Whether the qualifier/abbreviation provides further information on characteristics of the medicinal product (e.g. duration of action, devices, route of administration, animal population), which may help animal healthcare professionals to prescribe/select the appropriate medicinal product

It is the intention of the CVMP to produce an Annex to this guideline, containing examples of qualifiers/abbreviations acceptable to the CVMP.

- The potential consequences to the animal and risk to animal health, in case of medication error potentially related to the qualifier/abbreviation.

CVMP recommends applicants/MAHs not to propose qualifiers consisting of a single letter or number(s) (Arabic and Roman), because they may be confused with the strength and/or posology;

Qualifiers /abbreviations which require translation to be understood in the respective EU Member States are not acceptable as part of the (invented) name since this would be incompatible with the single name rule of Article 31(1) of Regulation (EC) No 726/2004.

The invented name should not convey any promotional message with respect to the therapeutic and/or pharmaceutical characteristics and/or the composition of the medicinal product.

The invented name should not appear offensive or have a "bad" connotation in any of the official EU languages. On a case-by-case basis, the CVMP may decide to inform the company of an identified concern without it automatically resulting in the rejection of the proposed invented name.

Use of upper-case letters in invented names should reflect the proposed/approved trademark registration.

The invented name of a fixed combination medicinal product should be sufficiently different from those of the individual active substances and/or those of other fixed combinations containing the same active substance(s).

CVMP recommends applicants/MAHs not to insert the whole invented name of the individual active substance(s) in the proposed invented name for the fixed combination.

For a medicinal product containing a prodrug, a different invented name from the invented name of the medicinal product containing the related active substance is required.

2.4. Addressing product specific concerns in proposed invented names

For **vaccines** composed of several serotypes when adding a new serotype the original invented name may be kept; the name is then followed by the number of serotypes present and the pharmaceutical form. The description of serotypes present is then listed in the qualitative and quantitative composition. An example of the format of the proposed invented name follows:

"Invented name" X serotypes suspension for injection.

The same applies when different types of antigens are added. This is of particular importance in situations where both vaccines are simultaneously available on the market in order to allow differentiation of the products.

For **biological medicinal products** in the case of manufacturing changes (for example leading to line extension etc.) leading to a new version of the medicinal product replacing the old one, consideration, on a case-by-case basis, should be given to maintaining the same invented name. When the characteristics of the medicinal product are altered (for example such as by the addition of a new adjuvant etc.), then a new invented name may be necessary.

For **non-prescription medicinal products**, due account should be given to the specific legal status of these medicinal products. Because of the absence of a prescription and/or the intervention by a healthcare professional, the (invented) name should aid selection/identification of the product by the animal owner and should minimise the risk of inappropriate use. In view of the above considerations, the specific criteria described under sections 2.1 to 2.3 may not apply here. An appropriate justification in this regard should be provided to CVMP for consideration. Qualifiers /abbreviations which require translation to be understood in the respective EU Member States are not acceptable as part of the (invented) name since this would be incompatible with the single name rule of Article 31(1) of Regulation (EC) No 726/2004.

In case of a switch from "**prescription**" to "**non-prescription**" status of an already authorised medicinal product it is up to the applicant/MAH to choose whether to retain the same invented name or to choose a new invented name. In exceptional cases, depending on the therapeutic context, the acceptability of the proposed invented name may be further considered by the CVMP during the evaluation process.

For **generic/hybrid/similar biological medicinal products** the same criteria apply as for any other medicinal products in respect to the invented name.

Where the applicant/MAH wishes to use instead of the invented name the **common name or scientific name**, together with a trademark or the name of the Marketing Authorisation Holder, they should take into account the following rules:

- If an INN recommended by the World Health Organisation exists it should be used within the name of the medicinal product exactly as published without omissions or abbreviations. All the linguistic versions of the INN shall be considered to be the same name. If one does not exist, the usual common name should be used.
- The 'name of the MAH' within the name of the medicinal product should correspond to the official name of the MAH as presented in the proof of establishment of the applicant/MAH.

3. Regulatory aspects related to the acceptability of proposed invented names

Invented names for variation/extension applications should be the same as those of the existing medicinal product in accordance with Commission Regulation (EC) No 1085/2003 as amended. In case the applicant wants to submit a separate marketing authorisation application for e.g. a new indication or target species, a different invented name shall be used.

4. Composition and Agency's procedure for checking proposed names

4.1. Agency's procedure for checking proposed invented names

The Agency operates a procedure to ensure that objections raised by National Competent Authorities against the (invented) name of a medicinal product due to potential safety risks or other criteria as defined in section 2 of this document are identified at an early point.

The practical experience of the Agency to date has shown that this early intervention and checking of the invented name(s) has permitted marketing authorisations to be granted without delays related to invented name issues.

The procedure for review of invented names can be subdivided into various phases, namely submission, consultation, discussion/adoption or rejection, and communication/clarification and follow-up.

4.1.1. 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 Agency of the proposed invented name(s) for their medicinal product (i.e. at the earliest 12 months and preferably 4-6 months prior to planned submission date of the marketing authorisation application).

To allow for review of proposed invented names, the Applicant(s)/MAH(s) are requested to send to the Agency (VMPname@ema.europa.eu) their proposed invented name(s) and the draft summary of product characteristics (SPC) or product profile and any information justifying the acceptability of the name(s). The 'Proposed Invented Name Request form' and further details of timing and content of an invented name application are available on the Agency website.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_00005_5.jsp&mid=WC0b01ac058002d9ac

Up to four invented names per marketing authorisation application can be proposed for consideration. However, the applicant is advised to indicate his preference, if any, so that the acceptability of any 'back-up' invented name can be considered without loss of time.

Multiple applications - Where the applicant submits proposed invented names intended to be used in the context of multiple Marketing authorisations/applications, the MAH should clearly indicate its intention, to allow the CVMP to review whether the proposed invented names are not potentially confusing with each other in addition to the review of the acceptability of the proposed name.

Invented names are usually submitted for initial marketing authorisation application(s). The (invented) name can also be changed at a post-authorisation stage, e.g. in case the invented name has not been accepted prior to the adoption of the opinion(s) by the CVMP or if the MAH wishes to change the name.

4.1.2. Consultation with the Member States and WHO

The proposed invented name(s) and all the background information provided by the applicant(s)/MAH(s) are sent to every contact point nominated by National Competent Authorities (NCA's) of EU- Member States, the European Commission (EC) and the World Health Organisation (WHO).

The NCAs, the EC and WHO are requested to inform the AGENCY of any objections/comments to the proposed invented name(s) on grounds of safety concerns or other concerns as described above within 30 days of receipt of such notification. It should be noted that invented name(s) may be checked against authorised, applied for, suspended and revoked /withdrawn medicinal products in the different Member States according to the relevant national legislation.

4.1.3. CVMP discussion/adoption

During the CVMP meeting the objection(s) and/or comment(s) to the proposed invented name(s) received from the different Member States, EC and WHO are reviewed. The group evaluates these objections/comments based on the criteria described above in section 2. If an objection is raised on the basis of similarity between the proposed invented name and an existing invented name, leading to a risk of confusion in print, handwriting or speech, the objection will always be evaluated taking into account other distinguishing factors as listed under 2.

After evaluation of all relevant factors, the CVMP will decide if the proposed invented name of a medicinal product may be accepted.

4.1.4. Applicant/MAH communication and follow-up

After the CVMP meeting, the applicant/MAH will be informed by the Secretariat of the outcome of the discussion on the acceptability of the proposed invented name(s) for their medicinal product(s) together with the reasons and source for the objection(s) raised. In case of objections to the proposed invented name(s), the applicant may justify the retention of the proposed invented name using the relevant justification form available on the Agency website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000055.jsp&mid=WC0b01ac058002d9ac

Such justification will thereafter be sent to all Member States for consideration, and comments received discussed at the subsequent CVMP meeting. The Member States who raised objections are requested to assess the justification and reconsider their objection.

During the CVMP meeting the maintenance or withdrawal of the previous objections to the proposed invented name(s), as well as comment(s) received from the different Member States, EC and WHO and the company's justification are reviewed.

If the proposed invented name cannot be accepted prior to submission, the Marketing authorisation application can be submitted either under any of the proposed invented names, 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 CVMP opinion on the concerned MAA the applicant will in such case have to inform the Agency (PM) and the Secretariat on the acceptable invented name of their choice.

If no suitable invented name has been identified at that stage, the opinion will be adopted according to the common name or scientific name accompanied by the name of the Marketing authorisation Holder.

4.1.5. Rejection by CVMP of a proposed invented name:

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 justify retaining the invented name addressing specifically all the objections raised. Such justification will need to include an assessment of potential for harm to the animal in case of a mix-up. This guideline should be taken into consideration, as appropriate, to address points for original objection.
3. Where new information, not previously brought to the attention of the CVMP becomes available to the applicant, the submissions of additional/subsequent justifications to the CVMP are considered acceptable.
4. If no invented name is accepted before adoption of the CVMP opinion, the opinion will be adopted under the common name or scientific name together with the name of the MAH.
5. In such a case, as soon as the Commission Decision is granted, the concerned MAH may submit a variation (section 3.2.6.1) to introduce an invented name, on the condition that such name has been considered acceptable by CVMP in accordance with the procedure described under Section 5.1.
6. Exceptionally, provided all means have been exhausted, the applicant/MAH may request the matter to be presented to the CVMP within the context of the evaluation of the medicinal product.

4.1.6. Post-authorisation issues related to invented names

Change of the (invented) name

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 procedure described in Article 5 of Commission Regulation (EC) No 1085/2003, for Type IB variations and the conditions described in the Annex I of the same Regulation.

Applicants are also advised to consult the European Commission Guideline on dossier requirements for Type IA and Type IB notifications – June 2006

http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-6/c/gdvartypiab_rev0_200307.pdf

Within 30 days of submission/validation of the Type IB variation (No.2), the AGENCY will inform the MAH of the outcome.

Taking into account that the MAH will be required to submit the AGENCY letter of acceptance of the concerned invented name as part of the variation application, it is recommended that the proposed invented name be submitted through the CVMP at least 4 months in advance of the intended Type IB (No. 2) variation application.

Other post-authorisation activities

Report of prescription errors/medication errors due to the invented names of medicinal products:

If prescription errors/medication errors due to the invented names of medicinal products (e.g. mix-up with another medicinal product) result in an adverse drug reaction (ADR) in humans or animals, such ADRs should be reported within the pharmacovigilance systems established at the side of the MAHs, within Member States and at EU level (for pharmacovigilance obligations see Regulation (EC) No 726/2004 and Volume 9 of the Rules Governing Medicinal Products in the EU) i.e. expedited or periodic reporting of adverse drug reactions in accordance with the legislation. Further it should be recognised that, where names convey misleading therapeutic connotations, there may be a risk for misuse or abuse of the product. Where such misuse or abuse leads to an ADR, reporting within the pharmacovigilance system applies.

Since medication errors due to the invented name do not necessarily result in an ADR, marketing authorisation holders and NCA should inform the Agency of any case reports concerning a centrally authorised medicinal product, which has been involved in a prescription error/medication error due to the invented name of the medicinal products. Such report should be submitted to VMPname@ema.europa.eu. In addition, with each PSUR, a summary report on medication errors, including those due to name confusion, occurring with the product should be submitted in accordance with the guidance provided in Volume 9 of the Rules Governing Medicinal Products in the EU.

Such single case and summary reports will be discussed within the Secretariat and if deemed necessary, by the Pharmacovigilance Working Party and/or Inspections Group. The results will be addressed to the plenary CVMP meeting if any regulatory action is deemed necessary. Such regulatory action could be e.g. a change in the invented name and/or communication to animal healthcare professionals.

5. Addressing transparency

On an annual basis, statistical and qualitative information on the outcome of the review of invented names is published in the Agency annual report.

6. General contact details

General invented name queries should be submitted to VMPname@ema.europa.eu

7. References and useful websites

7.1. References

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency:
http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf
- Directive 2001/82/EC, as amended of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-5/dir_2001_82/dir_2001_82_en.pdf
- Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93
http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_1993_2309/reg_1993_2309_en.pdf

7.2. Useful websites

- EMA Website: <http://www.ema.europa.eu>
- EMA Pre-authorisation Guidance document:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000055.jsp&mid=WC0b01ac058002d9ac
- WHO website: general: <http://www.who.int/en/>; information on INNs: <http://www.who.int/medicines/services/inn/innquidance/en/index.html>; and INN stems <http://www.who.int/medicines/services/inn/GeneralprinciplesEn.pdf>; <http://www.who.int/medicines/services/inn/FinalStemBook2006.pdf>
- EUR-LEX: <http://europa.eu.int/eur-lex/>

8. Abbreviations

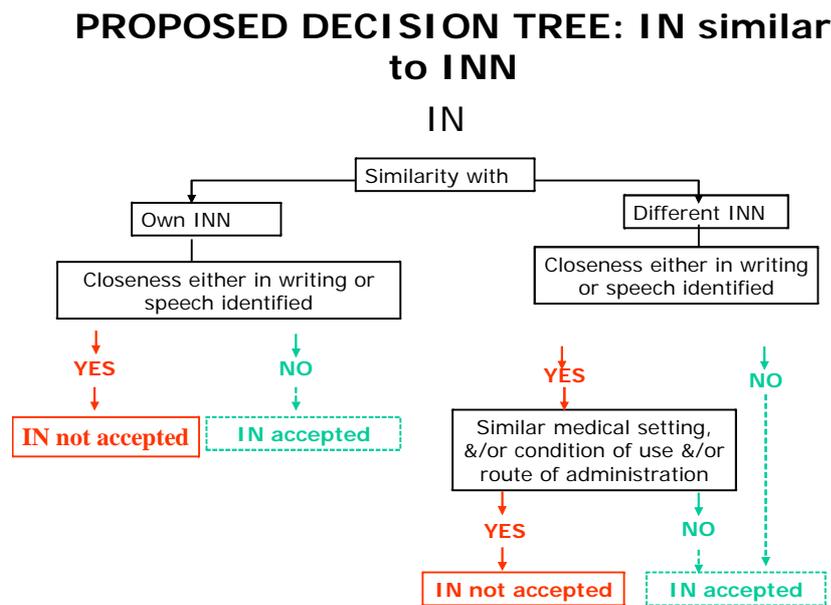
- **ADR:** adverse drug reaction
- **CVMP:** Committee for Medicinal Products for Veterinary Use
- **EC:** European Commission
- **EMA:** European Medicines Agency
- **EU:** European Union
- **MAH:** Marketing Authorisation Holder

- **NCA:** National Competent Authority
- **PM:** Project Manager
- **PhVWP:** Pharmacovigilance Working Party
- **SPC:** Summary of Product Characteristics
- **WHO:** World Health Organisation

Annex 1

Addressing international non-proprietary names (INNs)' concerns in proposed invented names (Ins)

1. Addressing similarity between an invented name and an INN (of the concerned medicinal product or a different one), the closeness either in writing or speech and the medical setting/condition of use/route of administration of the concerned medicinal products should be considered as follows:



2. Addressing the inclusion of an INN stem in an invented name (of the same medicinal product therapeutic class or a different one), the location of the INNs and the medical setting/condition of use/route of administration of the concerned medicinal products should be considered as follows:

PROPOSED DECISION TREE: IN containing INN stem(s)

