EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 June 2013
CPMP/328/98, Revision 6
Committee for Medicinal Products for Human Use (CHMP)

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

Draft

Draft agreed by NRG	10 April 2013
Adopted by CHMP for release for consultation	30 May 2013
Start of public consultation	07 June 2013
End of consultation (deadline for comments)	30 August 2013
Agreed by NRG	<Month YYYY>
Adopted by CHMP	<DD Month YYYY>
Date for coming into effect	<DD Month YYYY>

This guideline replaces the guideline CPMP/328/98, Revision 5.

Comments should be provided using this template. The completed comments form should be sent to NRG@ema.europa.eu

Keywords	***EMA, CHMP, NRG, invented name***

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Executive summary

Based on the experience gathered by the Name Review Group (NRG) since the last revision of the guideline in December 2007, it became apparent that some areas of the guideline would benefit from further clarifications, in particular with regards to the requirements for acceptability and submission of proposed (invented)[1] names of medicinal products processed through the centralised procedure.

This 6th update of the guideline further clarifies specific aspects of the criteria applied to address safety and public health concerns, international non-proprietary names issues and product-specific concerns in proposed (invented) names. Also, the procedure for submission of proposed (invented) names requests is streamlined and further clarified.

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 6 of Regulation (EC) No 726/2004 (ref1), *"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."*

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 patients and their access to the concerned medicinal product in that Member State. To obtain such derogation, the marketing-authorisation holder (MAH) 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 European Union 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(20) of Directive 2001/83/EC (ref2), 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(21) of Directive 2001/83/EC, as amended*, "The international non-proprietary name (INN) recommended by the World Health Organization, or, if one does not exist, the usual common name."*

According to the Article 4 of Council Regulation (EC) No 207/2009 on the Community trade mark (ref3), a trade mark may consist *"of any signs capable of being represented graphically, particularly words, including personal names, designs, letters, numerals, the shape of goods or of their packaging, provided that such signs are capable of distinguishing the goods or services of one undertaking from those of other undertakings."*

[1] In certain sections of this document reference is made to the terms '(invented) name', with the term 'invented' presented in brackets preceding the term 'name'. This format aims to cover two possible scenarios in terms of proposed names: a purely 'invented name'; and a 'name' which can be the combination of the INN together with the name of the MAH/applicant company or its trademark.

The review of trademarks is outside the European Medicines Agency's (EMA) remit. The EMA will not take into consideration aspects of intellectual property rights/trademark registration within its review for the acceptability of a proposed (invented) name. The applicant/MAH will need to contact directly the appropriate authorities to apply for a trademark registration.

The checking of the (invented) name is part of the EMA's role in evaluating the safety of medicinal products within the authorisation procedure, as the proposed (invented) name(s) could create a public-health concern or potential safety risk. Such an evaluation should be performed based on best available evidence and research.

Proposals for invented names as well as for names presented under the construction 'INN + company name/trademark' will be subject to EMA review. The latter case is not a default option in case no invented name for a specific product is accepted by the NRG. The 'INN + company name/trademark' option must also be submitted for review by the NRG (see section 6.4).

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 EMA's confidentiality policy and their own National or Authority rules of confidentiality.

2. Scope

The scope of this guideline is to provide applicants/marketing-authorisation holders (MAHs) with guidance on the criteria applied by the Name Review Group (NRG) when reviewing the acceptability of proposed (invented) names for medicinal products processed through the centralised procedure.

It provides details on the overall procedure for submitting and checking the acceptability of proposed (invented) names.

3. Legal basis

This guideline has been developed in accordance with Article 6 of Regulation (EC) No 726/2004 (ref1) and Article 1(20) of Directive 2001/83/EC (ref2), as amended, which require each authorisation application to include a single name not liable to confusion with the name of another medicinal product.

The EMA has established a review process performed by the Name Review Group (NRG) to ensure that the provisions set out in Article 6 of Regulation (EC) No 726/2004 and Article 1(20) of Directive 2001/83/EC are adhered to.

4. Criteria applied when reviewing the acceptability of proposed (invented) names

The following review criteria should be seen as general rules. The EMA may develop additional guidance on specific topics based on experience.

When reviewing the acceptability of proposed (invented) names, the NRG applies criteria based on public health concerns and in particular with regard to safety (section 4.1).

The applicant/MAH should ensure that the proposed (invented) name complies with the criteria outlined in this guideline before submitting a request to the EMA. To facilitate the review process, applicants/MAHs are advised to submit all available supporting documentation.

4.1. Addressing safety concerns and other public health concerns in proposed (invented) names

4.1.1. The (invented) name of a medicinal product should not be liable to cause confusion in print, handwriting or speech with the (invented) name of another medicinal product.

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

- The indication(s);
- The patient population(s);
- The pharmaceutical form(s);
- The route(s) of administration;
- The strength(s);
- The setting for prescription, dispensing and use;
- The legal status/classification for supply:
    - Medicinal product subject to medical prescription;
    - Medicinal product not subject to medical prescription;
    - Medicinal product subject to special medical prescription;
    - Medicinal product subject to restricted medical prescription;
    - Medicinal product subject to special and restricted medical prescription;
- Orphan (designation) status;
- (Potential) New pharmaceutical forms and/or routes of administration for the medicinal product concerned, as appropriate.
- Assessment of potential for harm to the patient in case of mix-up.

It should be noted that the NRG will consider potential for confusion of proposed (invented) names against authorised, applied for, suspended and revoked/withdrawn medicinal products in the different Member States according to the relevant national legislation regardless of the route of authorisation.

When considering potential for confusion with the name of a withdrawn/revoked marketing authorisation, in principle, a period of 5 years should have elapsed after the official invalidity of the marketing authorisation according to national legislation (e.g. publication in the official journal, etc.). This period could be reduced (e.g. the product was not marketed in EU for a period preceding this 5 year period) or extended (e.g. that the withdrawal of the marketing authorisation was linked to serious safety concerns and this has an impact on the potential risk to public health associated with the name) at the discretion of the NRG if it can reasonably be justified by the applicant/MAH.

The NRG also considers potential safety concerns and other public health concerns associated to the re-use of identical (invented) names. Specific assessment criteria applied by the NRG is available in the NRG position paper on the re-use of invented names of medicinal products (ref4).

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

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

4.1.4. Consideration should be given to the phonetics and the potential difficulties a proposed (invented) name may create in terms of pronunciation in the different EU official languages.

4.1.5. The use of qualifiers/abbreviations by letters as part of the invented name should in principle be acceptable.

The NRG 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 of the medicinal product. However, the use of numbers may in certain cases be acceptable, e.g. vaccines (see section 4.3.1). The applicant may consider providing the NRG with an explanation for their inclusion.

In considering the acceptability of a qualifier/abbreviation the NRG will consider the potential added benefit of the qualifier *versus* its potential risk to public health in case of medication error taking into consideration:

- Whether the qualifier/abbreviation provides further information on characteristics of the medicinal product (e.g. duration of action, devices, route of administration, composition, patient population) without being misleading or provides for a differentiation, which may help healthcare professionals and/or patients to prescribe/select the appropriate medicinal product.
- The applicability and use of the qualifier across all European languages. Qualifiers or abbreviations should not require translation to provide further information in the respective EU Member States.
- The potential risk resulting from more complex names, adversely affecting memorability, pronunciation and/or prescription of the medicinal product.
- Particularly in the context of non-prescription medicines, the importance of other elements such as labelling and pack-design should be taken into consideration to help on the selection of the medicinal product. These aspects shall be discussed at the time of the review of mock-ups/specimens. Should potential risk for public health be identified, the acceptability of the invented name may be subject to further assessment by the NRG.

4.1.6. 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.

4.1.7. The (invented) name should not appear offensive or have a 'bad' connotation in any of the official EU languages.

4.1.8. 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.

4.1.9. Applicants are advised not to submit proposed (invented) names that are very similar to each other (e.g. differing in one character) for a given marketing-authorisation application since any safety/public health concern identified with one name may apply to the other similar names and therefore increasing the likelihood of rejection.

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

According to Article 1(20) of Directive 2001/83/EC (ref2), *"… 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 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 an own or different INN or the inclusion of an INN stem into the proposed invented name(s).

The applicant/MAH is strongly advised to review INN similarity and/or INN stem inclusion before requesting that the proposed invented name(s) be considered for a medicinal product. 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 NRG will review the above cases on the basis of WHO World Health Assembly resolution (WHA46.19) on protection of INNs/INN stems to prevent any potential risk of confusion between invented names and common names.

4.3. Addressing product specific concerns in proposed (invented) names

4.3.1. For vaccines composed of several serotypes, when adding a new serotype the original invented name may be kept; it is recommended that the name is then followed by the number of serotypes present. 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 [number of serotypes]

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.

4.3.2. For radiopharmaceutical medicinal products the inclusion of target organs in the (invented) name should be avoided in order to prevent misleading connotations should an extension of the indication include new target organs.

In principle, numbers should not be used in the name to avoid confusion with the strength. In cases where the numbers appear in the radionuclide, these should be displayed in superscript, i.e. $^{\text{mass number}}$Element + [(Invented) name]

Numbers included as part of commonly known abbreviations are assessed on a case by case basis.

4.3.3. A sponsor may apply for designation of a medicinal product as an orphan medicinal product for an already approved medicinal product provided the orphan designation concerns an unapproved therapeutic indication. In this case, in accordance with Article 7(3) of Regulation (EC) No 141/2000 of 16 December 1999 on Orphan medicinal products (ref 5), and Commission Communication on the same Regulation (section C.2) (ref6), at the time of application for a marketing authorisation, the sponsor must apply for a separate marketing authorisation (with a different [invented] name) which will cover only the orphan indication(s).

When reviewing the acceptability of (invented) names for orphan medicinal products, the NRG applies the same approach as for non-orphan medicinal products. It is of particular importance

in these cases to provide detailed information on the specific setting in which the product is dispensed and used as well as on the target population.

4.3.4. For non-prescription medicinal products, due account should be given to the specific legal status of these medicinal products as defined in Articles 71 and 72 of Directive 2001/83/EC (ref2), as amended. The use of qualifiers/abbreviations within the invented name should aid selection/identification/differentiation of the product by the patient and should minimise the risk of inappropriate use.

In order to help self-selection and compliance by patients/consumers, it is acceptable that invented names have a positive connotation and/or be informative. The applicant may consider providing the NRG with an explanation for their inclusion.

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 vary/extend the existing marketing authorisation and consequently retain the same (invented) name or to submit a separate marketing-authorisation application under a different (invented) name (see section 5). In exceptional cases, depending on the therapeutic context, the acceptability of the maintenance of the existing (invented) name may be further considered by the CHMP during the evaluation process.

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

Special consideration should be given to the proposed (invented) name of a hybrid medicinal product to allow for differentiation when the latter differs in pharmaceutical form, strength, expression of active substance and/or indication from the reference medicinal product or other generics in the market.

4.3.6. 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/applicant, they should take into account the following rules:

- If an INN recommended by the World Health Organization exists for the active moiety 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, including translations officially recognised at the national level, shall be considered to be the same name. If one does not exist, the usual common name should be used.
- If a Modified INN (INNM) recommended by the World Health Organization exists for the active moiety, it should be used within the name of the medicinal product exactly as published without omissions or abbreviations.
- Where the active moiety is an unpublished INNM the name of the medicinal product should be that as agreed by users of INNs (pharmacopoeia, regulatory bodies, stakeholders), in accordance with the WHO INNM working document 05.167/3.
- The 'name of the MAH' within the name of the medicinal product should correspond to all or part of the official name of the MAH as presented in the proof of establishment of the applicant/MAH.
- For consistency reasons, ease in prescription by healthcare professionals and database entries, punctuation marks in between the INN and the name of the Company/trademark are not acceptable (with the exception of fixed combinations, where multiple INNs should be clearly separated by slash '/').

- The proposed (invented) name cannot be a mixture of legally available options: in accordance with Article 1(20) of Directive 2001/83/EC (ref2), the name should either be an invented name or the common name accompanied by a trademark or the name of the MAH.

4.3.7. Application for a CHMP Scientific Opinion in the context of collaboration with the World Health Organization (WHO) pursuant to Article 58 of Regulation (EC) No 726/2004 (ref1). Submission of proposed names to the NRG is not required since the product is not intended for use in the EU.

4.3.8. 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).

The NRG 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.

4.3.9. As multiple applications can have an independent life (e.g. may develop a different indication at a later stage), the proposed (invented) names of such applications have to be sufficiently different from each other to be allowed.

5. 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. The addition of a qualifier to an already in use invented name constitutes a different invented name, which would require submission as new marketing authorisation application.

In case the applicant wants to submit a separate marketing-authorisation application for, e.g., a new indication, a different (invented) name shall be used.

6. EMA procedure for checking proposed (invented) names

The EMA 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 4 of this document are identified.

The practical experience of the EMA 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.

6.1. Submission of the (invented) name request by the applicant/MAH

Provided that the medicinal product was deemed eligible by CHMP for evaluation under the Centralised Procedure the applicant should inform the EMA of the proposed (invented) name(s) for their medicinal product.

To allow for review of proposed (invented) names, the applicant(s)/MAH(s) are requested to send to the EMA (NRG@ema.europa.eu) their proposed (invented) name(s) and the draft summary of product characteristics (SmPC) or product profile and any other relevant information (e.g. multiple application justification, justification for deviation from the guideline, results of research in connection to similar invented names, patient information form distributed during clinical trials, etc.). The 'Proposed

(Invented) Name Request form' and further details of timing and content of an (invented) name application are available on the EMA website.[2]

Up to two proposed (invented) names per marketing-authorisation application can be accepted by the NRG.

In principle, where two proposed (invented) names have already been accepted by the NRG for a marketing-authorisation application, new requests for the review of additional proposed names under the same application will not be allowed. The NRG may, on duly justified grounds, allow the assessment of further proposed names in which case the applicant/MAH is required to indicate which two (invented) names should finally be maintained for a given marketing-authorisation application provided that they have been accepted.

In the case of rejection of proposed (invented) names, the applicant/MAH can submit a new request to the NRG for the review of new proposed (invented) names, provided that the number of finally accepted (invented) names will not exceed two (e.g. if one of the initially proposed two (invented) names has been rejected then the applicant/MAH is entitled to request the NRG to consider one more (invented) name).

The applicant/MAH should clearly indicate at the time of submission whether the proposed (invented) names are intended to be used in the context of multiple marketing-authorisation applications. This is to allow the NRG to review whether the proposed (invented) names are not potentially confusing with each other. As an exception to the general rule, up to two proposed (invented) names per duplicate can be accepted by the NRG in the context of multiple applications.

6.2. Consultation with the Member States

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 NCAs are requested to inform the EMA 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.

Representatives from the European Commission (EC) and the World Health Organization (WHO) and relevant experts selected from the European experts list may participate in the group's activities and consulted on a case by case basis regarding naming issues.

6.3. NRG/CHMP discussion/adoption

During the NRG meeting the objection(s) and/or comment(s) to the proposed (invented) name(s) received from the different Member States are reviewed. The group evaluates these objections/comments based on the criteria described above in section 4.

If an objection is raised on the basis of similarity between the proposed (invented) name and another (invented) name, leading to a risk of confusion in print, speech and/or handwriting, the objection will always be evaluated taking into account other distinguishing factors as listed in section 4.

After evaluation of all relevant factors, the NRG will decide if the proposed (invented) name of a medicinal product may be accepted or if further clarifications are to be submitted by the company. Its conclusions/recommendations are presented to the CHMP for adoption.

[2] See the 'Presubmission guidance' section of the Agency's website.

6.4. Applicant/MAH communication and follow-up

After adoption by CHMP, the applicant/MAH will be informed by the NRG Chair of the outcome of the discussion of the proposed (invented) name(s) for their medicinal product(s) together with the reasons and source for the objection(s) raised. It is emphasised that although objections due to conflicting names with existing medicinal products may have only been raised by the Member State(s) indicated in the outcome document, this does not exclude the possibility that the medicinal products referred to may exist in other Member States.

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 EMA website[3].

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

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

If the proposed (invented) name cannot be accepted prior to submission, the marketing-authorisation application (MAA) can be submitted either under any of the proposed invented names or the common name/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 have to inform the EMA (via the Product Team Leader) and the NRG secretariat about their choice of the accepted (invented) name.

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. However, such name also needs the NRG endorsement prior to adoption of the opinion; therefore sufficient time should be allowed for the NRG review to be performed (see section 1).

6.5. Rejection by NRG/CHMP of a proposed (invented) name

The applicant/MAH has the following possibilities:

1. To submit proposals for new (invented) names, which are checked through the same procedure as described above.

2. To justify retaining the (invented) name addressing specifically all the objections raised. The applicant/MAH should note that where objection(s) identified in the outcome fax were raised for conflicting names nationally authorised by the particular Member State(s), this does not exclude the possibility that the medicinal products referred to may exist in other Member States. The applicant/MAH should verify whether this is the case. The justification will also need to include an assessment of potential for harm to the patient in case of a mix-up. This guideline should be taken into consideration, as appropriate, to address points for the original objection(s).

Where new information not previously brought to the attention of the NRG becomes available to the applicant, the submissions of additional/subsequent justifications to the NRG are considered acceptable.

[3] See the 'Presubmission guidance' section of the Agency's website.

3. If no invented name is accepted before adoption of the CHMP opinion, the opinion will be adopted under the common name or scientific name together with the name of the MAH (section 6.4).

In such a case, as soon as the Commission Decision is granted, the concerned MAH may submit a variation (section 6.6.1) to introduce an invented name, on the condition that such name has been considered acceptable by the NRG in accordance with the procedure described under Section 6.

4. 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.

6.6. Post-authorisation issues related to (invented) names

6.6.1. Change of the (invented) name

The (invented) name can also be changed at a post-authorisation stage through a variation procedure, e.g. in case the (invented) name has not been accepted prior to the adoption of the opinion(s) by the CHMP or if the MAH wishes to change the name.

Post-authorisation procedural advice with regards to the change of (invented) name can be found at the EMA website[4].

6.6.2. Other post-authorisation activities

6.6.2.1. 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), 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, Directive 2001/83/EC and Good Pharmacovigilance Practices) i.e. expedited or periodic reporting of adverse drug reactions in accordance with the legislation (ref 1,2,7).

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.

NRG will take measures within its area of responsibility to prevent possible medication errors by close collaboration with the Quality Review of Documents (QRD) Group and the Pharmacovigilance Risk Assessment Committee (PRAC).

7. Addressing transparency

Periodically, the EMA publishes statistical information on the outcome of the NRG review on (invented) names.

8. General contact details

General (invented) names queries can be submitted to NRG@ema.europa.eu

[4] See the 'Post-marketing authorisation' section of the Agency's website.

Definitions

ADR: adverse drug reaction

CHMP: Committee for Medicinal Products for Human Use

EC: European Commission

EMA: European Medicines Agency

EU: European Union

MAH: marketing-authorisation holder

NCA: national competent authority

NRG: Name Review Group

PRAC: Pharmacovigilance Risk Assessment Committee

ROA: route of administration

SmPC: summary of product characteristics

WHO: World Health Organization

References and useful websites

1. 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.
2. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.
3. Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trade mark.
4. NRG position paper re-use of invented names of medicinal products.

   http://www.emea.europa.eu/docs/en_GB/document_library/Other/2011/07/WC500109576.pdf
5. Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.
6. Communication from the Commission on Regulation (EC) No 141/2000 on orphan medicinal products.
7. Good pharmacovigilance practices:

   http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp&mid=WC0b01ac058058f32c
8. Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products.
9. EMA pre-authorisation guidance document:

   http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000197.jsp&mid=WC0b01ac058002251c
10. EMA post-authorisation guidance document:

    http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000090.jsp&mid=WC0b01ac0580023398
11. EMA website: http://www.ema.europa.eu/ema/
12. Eur-Lex website: http://eur-lex.europa.eu/en/index.htm
13. WHO website: http://www.who.int/en/
14. Information on INNs: http://apps.who.int/medicinedocs/en/d/Jh1806e/5.html