European Medicines Agency
Evaluation of Medicines for Human Use

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REPORT FROM THE JOINT EMEA (NRG)/INTERESTED PARTIES MEETING 11 SEPTEMBER 2006

Chairman: Noël Wathion
Head of Unit
Post-authorisation Evaluation of Medicines for Human use

Background

EMEA hosted a Joint meeting with Interested Parties (AESGP, EFPIA and EGA) and NRG Member States representatives on 11 September 2006. The upcoming revision 5 of the 'Guideline on the Acceptability of invented names for human medicinal products processed through the centralised procedure', the implementation of the New Pharmaceutical Legislation, the consequences of the EU Enlargement, transparency issues and globalisation of requests for the review of invented names (IN) gave grounds for discussion for this fourth annual interested parties meeting.

The agenda and list of participants is attached (See **Annex I**).

Introduction

In his opening remarks, Noël Wathion (NW), Head of Unit Post-Authorisation Evaluation of Medicines for Human Use, clarified that the scope of the meeting was mainly to discuss, with the interested parties, the proposed amendments to the Invented name guideline. The amendments take into account the revised Community legislation which introduced explicit reference to the 'single invented name requirement' in the Centralised procedure as well as provided for definitions of the 'name of a medicinal product' and 'common name'. The other important aspect is the need to address the specificities of non-prescription medicines and generics given that the scope of the Centralised procedure has been extended to include these categories of medicines under certain conditions.

Other proposed changes take into account practice and experience gathered within the NRG since revision 4 of the guideline or is proposed to address increased complexity resulting from the enlargement of the EU, also in view to preparing upcoming enlargement to Romania and Bulgaria.

Participants were subsequently invited to introduce themselves. EFPIA, AESGP and EGA, thanked EMEA for hosting the meeting and looked forward to the discussion.

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Presentation from EMEA (See **Annex II)**

Zaide Frias (ZF), Chair of the NRG, introduced the following topics:

- The updated legal references and past practice in relation to the derogations by the EC to the single invented name requirement in the Centralised procedure. Such derogations being foreseen only in the exceptional cases where the proposed trademark has been cancelled opposed or objected to under invented name law in a member state and explicitly referred to in the revised Community legislation.

- She made reference to the increased complexity for the identification of a single invented name across the EU following the enlargement and Industry's repeated request for clear guidance and additional flexibility.

- She informed that the EC has acknowledged such impact and has requested the EMEA to reflect on a workable solution by reviewing the relevant parameters, including degree of similarity and standard of proof of objections on trademark grounds.

- The recent initiatives taken in order to increase transparency in relation to the NRG activities, its role and composition were mentioned, as was the intention to develop in the future a mandate, rules of procedure and work programme for the NRG.

- She then explained the different phases in the NRG procedure as well as highlighted changes introduced that aim at increasing the efficiency of the process.

- From statistical information on the outcome of the review process since revision 4 of the invented name guideline (period 1/05/05-30/06/06) it can be deducted that the NRG has an acceptance rate of 47 % on a total of 258 names compared to an acceptance rate of 65 % on a total of 368 names since revision 3 (period 1/07/02-30/04/05).

EFPIA expressed that, despite their shared interest of having one Worldwide brand name for their products, the high NRG rejection rate and the lack of flexibility in respect of the single name requirement was felt to be an additional obstacle for global naming efforts.

Nota Bene: at a separate Workshop held in the morning, EFPIA submitted a proposal for increased flexibility to the single trademark rule, through name variations. For details, please refer to the separate Report and Presentation available on the EMEA website.

The second part of the presentation was aimed at addressing the criteria for reviewing the acceptability of the invented names, distinguishing respectively the ones referring to safety concerns, other public health concerns, INN health concerns and product specific concerns. These were subsequently discussed in detail.

IN Guideline criteria - Safety concerns

The basic criteria that an invented name should not convey misleading, therapeutic or pharmaceutical connotations; be misleading with respect to product composition; be liable to confusion with the invented name of an existing medicinal product in print, speech or handwriting were acknowledged to be appropriate despite the existence of some overlap with the criterion that an invented should not convey any promotional message with respect to the use of the medicinal product.

AESGP stressed that for non-prescription medicines some form of promotional message is widely used and acceptable as not considered to resulting in any risk to public health. Should there be a need to maintain the criterion referring to 'promotional message', derogation for non-prescription medicines should be envisaged.

EFPIA informed that, under certain circumstances, the use of promotional qualifications such as "Plus" would be welcomed also for the prescription industry.

The parameters including the indication, pharmaceutical form, route of administration, legal status, orphan designation and now also the strength when reviewing proposed invented name were considered acceptable.

IN Guideline criteria – Other public health concerns

The proposed amendments to the criterion that an invented name should preferably consist of only one word, but that the use of short qualifications/abbreviations should in principle be acceptable provided an appropriate justification is provided was discussed.

Concerns were expressed in relation to the current wording of the guideline, which requires the qualifications/abbreviations to carry an established and relevant meaning in all Member states. It was acknowledged by all parties that finding a qualifier/abbreviation that meets this criterion has proved (almost) impossible.

Some NRG representatives stated however that certain qualification/abbreviations (e.g. Cold, Pain) would require to be translated in order to have a relevant meaning within their Member state. It was also proposed that patient organisations be involved in such discussions.

Industry representatives commented that from a legal point of view, qualifiers are not part of the trademark and that they could therefore be considered not to interfere with the single invented name requirement.

The EMEA suggested that it would discuss with the Commission as to whether the qualifiers could be regarded as not being part of the invented name and therefore be translated, where such translation should prove necessary. Alternatively it could be discussed whether such qualifiers could be added in the labelling information, separate from the name of the medicinal product. Industry and Member states representatives agreed.

In relation to the criterion that an invented name should not appear offensive or have a bad connotation in any of the EU languages, introducing the possibility for the NRG to decide, on a case-by-case basis, to informing the company without it resulting in a formal objection was endorsed. It was mentioned that this flexibility has already been applied by the NRG in recent practice.

There were no concerns expressed in relation to the existing criterion that the use of capitals in an invented name should reflect the trademark.

The proposed amendments to the criterion that the invented name for a fixed combination should be sufficiently different from that of the individual active substances or other fixed combinations containing the same active were discussed. It was stressed that the current Guideline requires the name to be completely different and that it was a new criterion introduced with revision 4 of the guideline.

EFPIA pointed out that the NRG has been applying the rule in an inconsistent way over the past years and that the practice within the NRG on this criterion would require clarification.

ZF acknowledged that the interpretation of this criterion has changed over time and was therefore not applied in a consistent way in the past. She also noted that it has resulted in a significant increase of the NRG rejection rate (acceptance rate of only 35 % on 42 proposed invented names for fixed combinations) not necessarily based on reasons for public health.

AESGP stressed that flexibility in relation to the naming of fixed combinations for non-prescription medicines is crucial and widely used at the Member State level.

There were no concerns expressed in relation to the existing criterion that the invented name of a pro-drug should be sufficiently different from the medicinal product containing the related active substance.

The proposed amendments in relation to extension applications include the update of the terminology in line with the variation regulation. It is also proposed, in case an applicant wants to file an extension application as a full standalone application, a separate MAA must be submitted under a different invented name as opposed to a completely different name.

Reference was also made to the Paediatric regulation that allows for a paediatric use authorisation to retain the existing brand name of the corresponding product authorised for adults, in order to capitalise on the brand recognition. It was stated that, as a result, EMEA could not continue to assert a public health concern linked to retaining the existing brand name for an authorisation other than for paediatric use.

In relation to the existing criterion that in the context of an extension application the same invented name as the existing medicinal product may be used, apart from the justified qualification/abbreviation it was clarified that, considering the difficulties in identifying a qualifier with an established and relevant meaning across the EU, this criterion has had limited use.

From statistical information on the grounds for objections it could be deduced that there has been an increase of objections related to similarity with existing invented names from 45% to 67%, which are not linked to any changes in the Guideline. The increase could be partially explained by the accession of 10 new Member States and the consequent increase of number of names that are potentially confusing with the proposed invented name. The same statistics show that there has been a significant drop in NRG objections related to similarity with INNs or inclusion of INN stems from 13 % to 2 % since the introduction of the decision trees. It was mentioned that the NRG has the intention to include these decision trees in the revision of the guideline for transparency reasons and to allow companies to present justifications for deviations in this respect.

The objection rates based on other parameters such as the use of qualifiers, promotional/misleading message and pro-drugs seem to remain stable.

IN Guideline criteria – INN/INN stem health concerns

Participants were informed that the NRG applied a strict policy in relation to similarities with own and different INNs as well as rejected the inclusion of INN stems within proposed invented names. The resulting significant rejection rate resulted in the application, in July 2004, of decision trees which, despite having been made public at the interested parties meeting, were not included in the Guideline. The proposal to include the decision trees within the revision 5 of the Guideline was welcomed, as it provides additional transparency in the NRG activities but also allows for companies to submit justifications for deviations.

EFPIA commented that certain short and simple/weak INN stems should be allowed for use, such as –ac, -ium, -tide (see slide 19) as they are already contained in numerous trade marks. To exclude those stems in an invented name would limit the creation of new trademarks, without real safety justification as those syllables are very common in all EU languages and are not therapy specific.

ZF added that companies would in any case need to provide a justification for the inclusion of INN stems within their proposed invented name and, where necessary, the NRG Secretariat would liaise with the WHO to determine acceptability. She concluded that this matter would be looked into in the context of the upcoming revision but that it is not expected to introduce greater flexibility other than that introduced already with the INN/INN stem decision trees.

IN Guideline criteria – product specific concerns

There were no concerns expressed in relation to the existing product specific criteria for vaccines, biological and orphan medicinal products.

The proposal to introduce product specific criteria for non-prescription medicinal products was discussed.

The need to take due account of the specific legal environment associated with this category of medicinal products and the differences in diagnosis, selection/identification of the appropriate medicinal product by the patient/pharmacist and the absence of a 'prescription-dispensing' transcription phase justify the non-applicability of specific limitations described in relation to qualifiers, promotional message and fixed combinations. It was stressed that companies would nevertheless be requested to provide the appropriate justifications to the NRG. Such justification could include e.g. the benefit to the selection/identification process by the patient and lack of inappropriate use.

AESGP explained that companies have the possibility of using "umbrella brands" (i.e., the same brand name for different non prescription medicinal products), all over Europe and that the possibility to use "umbrella brands" also under the centralised procedure would be important. It was explained that "umbrella brands" might be beneficial from a public health perspective in guiding the consumer when choosing a non-prescription medicine and practising responsible self-medication.

The already existing criterion offering the possibility for companies in case of switch from 'prescription' to 'non-prescription' to retain the same invented name or to choose a new one did not raise any concerns.

It is proposed to add that in exceptional circumstances, depending on the therapeutic context, the acceptability of the proposed invented name may be further considered as part of the review process by the CHMP. No objections were raised.

It was stated that the Guideline would in relation to invented names for generic/hybrid/similar biological medicinal products require the same criteria to be applied as for any other medicinal product.

It was further clarified that where an applicant/MAH wishes to use instead of the invented name the common name/scientific name and a trade mark or the name of the MAH, that the INN recommended by WHO should be used exactly as published. Where such INN does not exist, the usual common name should be used. It was also suggested that the use of hyphens and/or other symbols would not be allowed.

A discussion took place on how to represent the 'name of the MAH' (i.e. whether or not to include the character of corporate personality) and how to interpret 'trademark' (trade marked representation of the company name or broader).

EGA stated that these concepts should preferably be interpreted such as to allow maximal flexibility also in view of the very different prescribing practices across the EU. This would also include flexibility in respect of pack design to accommodate these differences in the individual member states.

Proposals for future developments

The following additional points were addressed and discussed:

EFPIA (S. Marino) asked whether NRG decisions by qualified majority voting (QMV) had been considered. NW stated that while rules could be changed that it is preferable to work by consensus to avoid blocking at Standing Committee level, as was the case in the past. Tony Humphreys (TH) added

that the NRG, as a satellite group with an advisory capacity, did not comprise 25 Member States delegated so voting by majority would not be appropriate.

The possibilities to appeal the NRG decisions by means of an oral explanation to the NRG were discussed. TH stressed that this would entail a change in the organisation of the NRG meetings (e.g. timing and duration) so that companies need to indicate what added value it would present.

EFPIA queried whether naming principles for 'advanced therapies' were being discussed in the upcoming revision of the guideline. NW stated that any contributions in this respect from Industry would be welcomed.

The possibility for publication of rejected names was queried. TH responded that information on pending applications is considered confidential. NW mentioned that the request to have transparency on agendas including the names of products under evaluation is currently under discussion with Heads of Agencies in the context of agreeing policies on access to documents.

Conclusions

Noel Wathion thanked all participants to the Workshop for their contribution and informed that the next steps would include the development of the single name rule exceptions, the discussions of the proposed amendments to the Guideline with NRG, CHMP and the European Commission in order to allow for the release for consultation at the latest in 1Q2007.

He also proposed that the agenda, meeting report and presentations of this meeting would be released on the EMEA website after it has been shared with the attendees for their agreement.

All interested parties looked forward to pursuing the excellent collaboration.

A.O.B:

Presentations received from EFPIA and AESGP in support of the discussions are attached (See **Annexes III and IV**).