EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Mandate, objectives and rules of procedure for the Name Review Group (NRG)

1. General considerations

According to the CHMP rules of procedure, the Committee may consult its working parties on any scientific issue related to their specific fields of expertise. The Committee may also delegate certain tasks associated with the scientific evaluation of applications, or drafting of guidelines to the relevant working parties. The tasks identified by the Committee should be included in the work programme of each working party to be adopted by the Committee.

From January 1995 until October 1999, (invented) names were reviewed by the CPMP during their monthly meetings.

In October 1999, the Committee agreed to set up a Satellite Group of the CPMP initially called "Tradename Review Ad Hoc Group" (TRAHG), currently known as "Name Review Group" (NRG) to perform the review of names and identify potential difficulties, from a safety/public health point of view, presented by the (invented) name(s) proposed by an applicant. Being a Satellite Group of the CHMP, the NRG will only deal with (invented) names for human medicines.

2. Mandate and objectives

The group is responsible for:

- Review of (Invented) Names requests for human products submitted via the centralised procedure

To review the Applicants'/Marketing Authorisation Holders' (MAH) proposed names for the centralised procedure, from a safety/public health point of view, as stated in the Guideline on the acceptability of names for human medicinal products processed through the centralised procedure (EMA/CHMP/287710/2014 – Rev. 6).;

- Guidance

To update the NRG guideline where/when appropriate, and to create and maintain other relevant guidance documents;

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- Exchange of information/cooperation with EMA Working Parties/Groups, international partners and other stakeholders

To take measures within its area of responsibility to prevent possible medication errors by close collaboration with the Quality Review of Documents Group (QRD), the mock-ups and specimens team, the Pharmacovigilance Risk Assessment Committee (PRAC) and other working parties and groups if deemed necessary;

To make recommendations to the CHMP in relation to critical issues discussed in the NRG plenary meetings;

To liaise with interested parties (e. g. EFPIA, EGA) through regular meetings in order to share experience and exchange information; and

To collaborate with international partners, such as the FDA, Health Canada, or the WHO, regarding naming issues.

3. Composition and rules of participation

The NRG is chaired by an Agency representative and is composed of representatives from the NCAs. The secretariat of the NRG is also ensured by the Agency. Additionally, representatives from the European Commission (EC), the World Health Organisation (WHO) and relevant experts selected from the European experts list may participate in the group's activities.

The expertise of the group should also cover areas such as:

- regulatory affairs
- practising/academic pharmacy
- medication errors
- pharmacovigilance

Members of the core group shall be nominated by the national competent authorities on the basis of their specific scientific expertise and/or regulatory experience on the subjects covered within the scope of the group's mandate. The number of core group members attending in person the meetings shall not exceed 16 and they shall cover, as much as possible, the different language groups across Europe.

Membership of the NRG implies a commitment to participate actively in the work of the NRG and for all of those who are attendees, also participate in the entire meeting regularly.

A member may nominate an alternate to participate in those exceptional cases where he or she is unable to attend a meeting.

Whenever possible, any given member should be replaced by the same person (alternate) in order to maintain continuity. The member shall inform the NRG secretariat at the latest one week in advance of the meetings if he/she will be replaced by the alternate. The list of alternates will be made available to the CHMP.

Members who wish to bring additional experts should consult the NRG Secretariat and the Chairperson in advance of the meeting.

Certain Agency staff may be designated as contact persons with other working parties and/or scientific advisory groups to ensure good communication in areas of common interest. The concerned working

parties will agree on the responsibilities of the contact person. The NRG will agree on the responsibilities and role of the contact person.

4. Meeting frequency

The NRG shall meet up to 6 times per year (approximately every 2 months). Plenary meetings can be organised at the Agency premises or alternative making use of virtual meeting systems. Its conclusions shall be presented for adoption at the following CHMP meeting. In addition, teleconferences can be organised in between meetings in order to discuss guidelines and other non-product related issues.

5. Rules of procedure

5.1. Responsibilities of Chairperson

The Chairperson, and if appointed, in his/her absence the Vice-Chairperson, is responsible for the efficient conduct of the business of the NRG and shall in particular:

- plan the work of the NRG together with the NRG secretariat,
- monitor, together with the NRG Secretariat, that the rules of procedure are respected,
- ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the NRG,
- aim to achieve consensus on issues discussed by the NRG,
- decide in exceptional cases, when a vote is necessary,
- ensure, together with the NRG and the NRG Secretariat, the regulatory and scientific consistency of the NRG's recommendations,
- co-ordinate, together with the NRG secretariat, the work of the NRG with that of other relevant working parties/groups of the Agency,
- report on the activities of the NRG to the CHMP or other working parties/groups as appropriate.

5.2. Election of chairperson

The Chairperson, and the Vice-Chairperson if appointed, of the NRG is nominated by the Agency.

5.3. Organisation of meetings and reporting arrangements

- The NRG shall meet regularly at the Agency.
- The dates of meetings are decided on an annual basis in consultation with the NRG and the relevant Committee(s).
- The meetings will be held, and minutes produced, in English.
- The draft agenda for every meeting shall be circulated to the NRG members (contact points and attendees), together with the relating documents, by the NRG Secretariat, in consultation with the

chairperson, no later than 1 week in advance of the NRG meeting. After each meeting the table of decisions (minutes of the meetings) is circulated as well to the NRG members.

- After every NRG meeting, the table of decisions is presented for adoption at the following CHMP meeting.
- When agreed by CHMP, the decisions will be included in a database of all accepted names that NRG members will be able to access to ensure that up-to-date advice can be provided for National Applications.
- When a member of the NRG (attendee) is unable to participate in a meeting, part of a meeting or discussion topic due to conflict of interest, he/she must inform the NRG Secretariat in writing in advance of the meeting.
- The NRG may identify and propose topics for consideration by the group. Any proposal for a guideline, providing adequate justification, shall be transmitted to the relevant Committee(s) for endorsement and shall be preceded by a concept paper to be endorsed by the Committee(s).
- The mandate of the NRG will be prepared by the NRG Secretariat and agreed by the NRG group. It will be adopted by the CHMP, and it shall be reviewed at the end of every 3 year.

5.4. Drafting groups

When further consideration is required in order to prepare proposals on specific topics, the NRG may convene drafting groups constituted of members of the NRG or experts, as appropriate, usually via teleconference.

- The drafting group will report to the NRG in direct line.

5.5. Participation of experts in meetings

When necessary, the NRG may avail itself of the services of experts in specific scientific or technical fields. Such experts shall have proven experience in the assessment of medicinal products or in their field of expertise and be included in the European Experts list. When appropriate, members from patients'/consumers' and healthcare professionals' organisations may act as experts.

The names of these experts shall be notified to the NRG Secretariat before the meeting, which they are due to attend.

5.6. Guarantees of independence

The members of the NRG and experts referred to above shall not have any direct interests in the pharmaceutical industry, which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests, which could relate to the pharmaceutical industry, shall be entered in a register held by the Agency, which is accessible to the public, on request at the Agency's office.

Members of the NRG and experts attending these meetings shall declare at the beginning of each meeting any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be made available to the public.

The specific provisions for handling declaration of interests and confidentiality undertakings as defined in the Policies on the handling of conflicts of interests are applicable to members of the NRG and experts participating in the activities of the NRG.

5.7. Code of conduct

Members of the NRG and experts participating in the Agency's activities shall abide by the principles set out in the EMA Code of Conduct.

5.8. NRG secretariat

Under the authority of the Executive Director, the NRG Secretariat shall provide technical, scientific and administrative support to the NRG. This includes the following:

- provide/coordinate technical, legal, regulatory and scientific support to members of the NRG,
- prepare and co-ordinate the work in consultation with the Chairperson,
- ensure, if appropriate, that the periods laid down by Community legislation for the adoption of the opinions are complied with,
- organise meetings of the NRG ensuring timely circulation of meeting documents,
- facilitate the necessary contacts between the NRG, the CHMP, PRAC and other concerned working parties and/or scientific advisory groups,
- contribute to the overall quality assurance of regulatory consistency of the documents/recommendations of the NRG in co-operation with the Chairperson or Vice-Chairperson, as appropriate,
- prepare the minutes of the meetings of the NRG in consultation with the Chairperson,
- communicate, when necessary, any Committee recommendations relevant to the NRG to interested parties,
- contribute to the identification of experts,
- publish statistical information on the outcome of the NRG review on (invented) names as part of the CHMP monthly report and, on an annual basis, in the EMA annual report.

5.9. Contacts with interested parties

Pharmaceutical industry, healthcare professionals, patients/consumers or other interested parties have the opportunity to comment in writing on draft guidelines and general regulatory developments during the public consultation of the documents.

When considered appropriate by the NRG, oral presentations by interested parties can be made during NRG meetings with interested parties.

Before any consultation session, interested party representatives and group members will communicate to the NRG Secretariat the points they would like to discuss. Therefore, an agenda of the session can be prepared for agreement by the NRG Chairperson.

5.10. General provisions

The Members of the NRG, as well as observers and all experts, shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by individual professional secrecy.

When participating in international or other fora on behalf of the CHMP, the NRG members shall ensure that the views expressed are those of the CHMP.

When participating in international or other fora not specifically on behalf of the CHMP, members shall make clear that the views expressed are their own views and not those of the CHMP.