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Mandate and objectives for the EMA Working Party on Quality Review of Documents (QRD)

1. General considerations

The European Medicines Agency (EMA) created an *ad hoc* Working Group on Quality Review of Documents at the proposal of the European Commission at the Pharmaceutical Committee meeting of 29 February 1996. The objective of the Group was to facilitate the streamlining of the European Decision-Making process in the context of the handling of product information and provision of relevant guidance and standardisation, without prejudice to the competencies of the scientific committees or other fora such as the Standing Committees for human and veterinary medicines.

2. Mandate and objectives

- Product specific linguistic review for human and veterinary medicinal products

To review the English product information annexes with the aim to ensure compliance and consistency with the rules set out in various guidance documents, including, but not limited to the SmPC guideline and the QRD annotated template.

To verify terminology used in translations of product information via the centralised and arbitration/referrals procedures and its consistency/linguistic accuracy with the reference documents.

- Guidance and terminology standardisation

To establish common principles with the aim to harmonise different aspects of product information addressing, amongst others, patient safety, availability of medicines and readability.

To ensure linguistic and other formal coherence and consistency between different terminology used in product information for human and veterinary medicinal products approved via the centralised and arbitration/referrals procedures. The QRD Working Party (WP) shall also seek to promote initiatives towards the standardisation of the use of terms, inter alias through co-operation with the European Directorate for the Quality of Medicines (EDQM) and the Translation Centre for the Bodies of the European Union (CdT, Luxembourg) as well as in the context of cross-Agency terminology projects.

- Templates

To review and update product information templates both to ensure compliance with EU rules and guidelines on medicinal products and take into account practical experience and regular feedback

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received from third parties. This includes advice to scientific committees when developing core SmPCs and core package leaflets for a specific therapeutic area.

- User consultation with target patients group

To promote legibility of patient information by providing support in the assessment of user testing results submitted by the pharmaceutical companies. The QRD WP shall develop guidance and templates for the assessment of user testing reports and ensure a consistent approach across national competent authorities.

To monitor, analyse and produce statistics on user testing in the context of the centralised procedure.

- EU Enlargement

To take all necessary steps in order to prepare EU candidate countries for a smooth integration in the European regulatory system in areas related to product information.

- Exchange of information/cooperation with EU institutions/groups/bodies, international partners and other stakeholders

To provide advice at the request of scientific committees, working parties, national competent authorities (NCAs) or the Commission, in particular with a view to contribute to the development of common understanding on the implementation of legislation and guidelines.

To enhance the cooperation with patients' and consumers' organisations as well as with healthcare professionals by involving them during the product information review.

To work closely with the European Commission in areas of responsibility set out in this document.

To work in collaboration with CMDh and CMDv in order to harmonise practices across Member States and exchange information in areas of common interest, especially in the context of user testing and development of core SmPCs and product information templates.

To establish channels of communication with FDA, Health Canada and other non-EEA health authorities in areas of common interest.

To share experience and views with stakeholders and involve/consult them in the development of relevant guidance/templates.

- Medication errors

To take necessary steps towards the prevention of medication errors in the context of product information review through ongoing liaison with the Name Review Group (NRG), the EMA mock-up and specimen reviewers as well as the Risk Management Plan specialists.

- Support availability of medicines and simplification of labelling

To provide support in facilitating the availability of centrally authorised medicines across the EEA by means of considering labelling exemptions/simplifications within the given EU legal framework.

3. Composition and rules of participation

The QRD Working Party is chaired by an EMA representative, nominated by the EMA for 3 years.

The QRD WP is composed of the following members and observers:

- One representative per Member State (plus Norway and Iceland) for both human and veterinary medicines with experience in regulatory affairs and the linguistic field and with a scientific background, designated by the NCA.
- One representative from the European Commission.
- One representative from the Translation Centre for the Bodies of the EU (as observer).
- EMA (chair and secretariat).

Members of the QRD WP may nominate an alternate representative to participate in those cases where the official representative is unable to attend a meeting.

The representative of the Member State has the responsibility to liaise with their NCA, as necessary, in order to provide the position of the NCA on the topics to be addressed. It is also their responsibility to inform their NCA about the activities of the Party.

4. Meeting frequency

The QRD WP meets up to 4 times per year in its plenary format. Plenary meetings can be organised at the Agency premises or alternative making use of virtual meeting systems. The dates of the meetings shall be published on the Agency's website.

QRD sub-group meetings dedicated only to the review of product information may be held once a month, if necessary. QRD sub-group meetings will mainly be organised via teleconference.

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 QRD WP and shall in particular:

- plan the work of the QRD WP together with the QRD Secretariat,
- monitor, together with the QRD 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 QRD WP,
- aim to achieve consensus on issues discussed by the QRD WP,
- decide, in exceptional cases, when a vote is necessary,
- ensure, together with the QRD WP and the QRD Secretariat, the regulatory and scientific consistency of the QRD's recommendations,
- co-ordinate, together with the QRD Secretariat, the work of the QRD WP with that of other relevant working parties/groups of the Agency,
- inform the CxMP, CMDh and CMDv or other scientific committees or working parties/groups as appropriate on the activities of the QRD WP.

5.2. Organisation of meetings and reporting arrangements

- The dates of meetings are decided on an annual basis in consultation with the QRD WP.
- The meetings will be held and minutes will be written in English.
- The draft agenda for every meeting shall be circulated to the QRD WP (contact points and actual attendees), together with the relating documents, by the QRD Secretariat, in consultation with the Chairperson, no later than 1 week in advance of the QRD meeting. After each meeting the minutes of the meetings are circulated as well to the QRD members within a month.
- When a member of the QRD WP (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 QRD Secretariat no later than the start of each meeting.
- The QRD WP may identify and propose topics for consideration by the members. 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 QRD WP will be prepared by the QRD Secretariat and agreed by the QRD WP. It will be adopted by the CHMP and CVMP. It shall be reviewed at the end of every 3 year.

5.3. Drafting Groups

- When further consideration is required in order to work on specific topics the QRD WP may convene drafting sub-groups constituted of members of the Party or additional participants, as appropriate.
- The drafting sub-group will preferably be held in the margin of a QRD plenary meeting, or alternative via teleconference, and will report directly to the QRD WP at its plenary format. A written report shall be provided.

5.4. Participation of experts in meetings

When necessary, the QRD WP 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.

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

5.5. Guarantees of independence

The members of the QRD WP 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 QRD WP 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 QRD WP and experts participating in the activities of the QRD.

5.6. Code of conduct

Members of the QRD WP participating in the EMA's activities shall abide by the principles set out in the EMA Code of Conduct. The members of the Party are bound to confidentiality with regard to the discussions held during the meetings of the QRD WP and the work undertaken within the framework of the Group.

5.7. QRD Working Party secretariat

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

- provide/coordinate technical, legal, regulatory and scientific support to members of the QRD WP,
- prepare and co-ordinate the work in consultation with the Chairperson,
- organise meetings of the QRD ensuring timely circulation of meeting documents,
- facilitate the necessary contacts between the QRD WP, the CxMP and other concerned working parties and/or scientific advisory groups and/or others,
- contribute to the overall quality assurance of regulatory consistency of the documents/recommendations of the QRD WP in co-operation with the Chairperson or Vice-Chairperson, as appropriate,
- prepare the minutes of the meetings of the QRD WP in consultation with the Chairperson,
- communicate, when necessary, any Committee recommendations relevant to the QRD to interested parties,
- contribute to the identification of experts.

5.8. 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.
- The QRD WP shall organise workshop meetings with stakeholders to discuss issues of common interest.

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

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

5.9. General provisions

The Members of the QRD Group, as well as observers (CdT) 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 EMA/scientific committees, the QRD members shall ensure that the views expressed are those of the EMA/scientific committees.

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