EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Linguistic aspects and preparatory steps before accession in the EU

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An agency of the European Union

General introduction

Linguistic aspects of Product Information (PI) are handled within the Quality Review of Documents group (QRD). QRD was established in June 1996.

Composition:

- European Medicines Agency (chair & secretariat)
- Member States (1 Human + 1 Vet)
- European Commission
- Norway + Iceland (as observers)
- Translation Centre, based in Luxembourg

QRD mandate (under review)

- To ensure clarity, consistency and accuracy of the medicinal product information and of its translations.
- To verify the terminology used in translations.
- To promote legibility of patient information.
- To contribute to the development of common understanding on the implementation of legislation and guidelines.

Product Information Templates

The QRD templates*,

➢Set out the standard headings and indicate the most commonly used standard phrases and terms in the 22 official EU languages (plus NO and IS). Define the format and layout for the 3 Annexes (see below).

➢Annotated EN template -> supplements guidance already provided in the SPC guideline, Packaging guideline.

* *Annex I: Summary of Product Characteristics (SPC),*
  Annex II: Conditions of marketing,
  Annex IIIA: Labelling,
  Annex IIIB: Package Leaflet (PL)

QRD areas of activities

- Product Specific or General Issues
- **User testing**
- Standard terms
- Legislation, Guidance/Reference documents updates
- Translation services/CdT
- **Product Information Quality Review**

User Testing: EMA approach to User Testing

- **Demonstrate** that patients can **locate** information in the package leaflet, **understand** it and **know how to act** upon it.
- **User testing is mandatory**, and part of the scientific assessment.
- Post-authorisation procedures with significant impact on the package leaflet → trigger user testing**.**

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PI Quality Review - Pre-Opinion phase

A. During the evaluation process English only PI (SPC, Labelling and PL) will undergo a preliminary "technical" check by EMA staff => template compliance, correct location of information, linguistic issues, etc.

B. After clock stop the EN PI will again undergo a linguistic review by both the Member States and EMA (QRD sub-group meeting to be held at the request of the applicant).

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PI Quality Review - Post-Opinion phase

- 5 days after positive opinion by the scientific committee Member States will review the quality of translations of PI within 14 calendar days.
- Comments to be submitted electronically
- Any issues to be addressed directly with the company.
- Central coordination of the process by the Agency.

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Preparatory steps to integrate new MS in the translation framework

Facts

- European Commission decisions on Marketing Authorisations will extend automatically to the territory of a new MS as of date of accession.
- Marketing Authorisation Holders (MAHs) are legally obliged to provide translations in the new official language(s) as of date of accession.
- Availability of translations is an essential requirement for future and ongoing regulatory activity.

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Objectives

- To ensure a good standard of quality of translations and to avoid potential public health concerns.
- To avoid delays of supply of relevant medicinal products in accession countries.

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Role and tasks of the different stakeholders

- The Agency will initiate and coordinate the different stages of the linguistic review process.
- MAHs will be requested to prepare and submit linguistic versions in **the new language(s) at the same time**.
- National Authorities will be invited to perform the linguistic check of the translations.

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THANK YOU FOR YOUR ATTENTION!

ANY QUESTIONS?