



Making Medicines Affordable

Quality of Translation



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Quality of translations- follow up

- Commitment from industry to tackle this issue
 - Dedicated session at the EGA Regulatory Conference- January 2011
 - Experience of some MS (DK, CZ, PT) and industry
 - Feedback from industry on questions raised by the authorities



The feedback on questioning the quality of translation (1)

- In general two types of comments:
 - Related to used terminology.
 - Standard terms dictionary to be used (EMA?)
 - Regularly published PAR, SmPC, PIL of Ref Product
 - Linguistic/style comments from individual assessors
 - very subjective/ personal linguistic style; should be left to the applicant.

The feedback on questioning the quality of translation (2)

- To improve understanding in the national languages do we divert from what was agreed?
 - e.g. A short sentence in English can result in multiple sentences in national language e.g. German, Dutch. Better to avoid literal translation and get correct sense in a more concise way in national language
 - Agreed texts not always optimal in English
 - IMB and MHRA have proposed changes to agreed PIL texts during national phases

The feedback on questioning the quality of translation (3)

- Applicants would appreciate a clear feedback from NCA on issues that are considered to be good and bad quality translations
- Positive experience from MS to be promoted broadly
- Industry to be more critical in its choice of translators



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Challenging timelines

- **Timelines challenging for both sides:**
 - MS to adopt a decision at national level within 30 days (Art 28.5 of Dir 83/2001)
 - Applicant to submit high quality national translations of the SPC, PL and labeling and mock-ups, if necessary, no later than 5 days after the procedure is closed (CMD(h) guideline)
- **Possible impact of quality of translation of finalisation of the national phase of DCP/MRP**

Finalisation of the national phase

■ Gentleman's agreement:

- if translation is received within 5 days, the MA should be treated as priority and issued within legal timeline

■ Granting of MA on the basis of English text

- the translation as a follow up measure if the product is not planned to be marketed immediately
 - system already in SE, AT and NL

- allows the request for price and reimbursement⁷



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Translation after referrals

- Final wording for both SmPC and PIL plus translations always to be provided by the competent authority
 - Already positive experiences with e.g. BfArM, AGES, MEB where translations are on the web site increases harmonisation of information for patients
 - Text to be implemented usually not too long
 - Reduction of unnecessary workload for NCAs checking of translations and for industry



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Thank you!

