



Work instructions

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| Title: QRD forms 2 (former Linguistic Check Forms) | | |
| Applies to: Secretaries in the Human Medicines Development and Evaluation Unit, Patient Health Protection Unit, Veterinary Medicines Sector and QRD Secretariat | | |
| Status: PUBLIC | | Document no.: WIN/EMA/0098 |
| Lead Author | Approver | Effective Date: 15-DEC-10 |
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| Signature: On file | Signature: On file | Supersedes: WIN/EMA/0098 (05-MAY-09) |
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1. Changes since last revision

WIN title changed from 'Linguistic Check Forms' to 'QRD forms 2 (former Linguistic Check Forms)' Updated to reflect the new organisational names in the Agency, the new corporate identity and change from EDMS to DREAM.

Amended to reflect changes to the PIPIT Guidance rev. 4, in particular replacing Linguistic Check Forms (LCF) with QRD forms 2 throughout the document and renaming 'PTL secretary/VET PM' to 'Secretary'. Deleted reference to day 232/+22 throughout the document and the related footnote.

Revision of the following steps:

- step 3 (section on naming of files moved from step 5 to step 3)
- step 4 (reworded 'Fill in the LCF' to 'Fill in section 2 of the QRD form 2'; added 'No other symbols should be used in this section'; symbols updated)
- step 5 (reworded 'Save LCF in EDMS' to 'Check in the QRD form 2 in DREAM as a new version and link it')
- step 6 (email address of the QRD Secretariat updated)

2. Records

See step 3 and 5 of the Instructions.



3. Instructions

DREAM: Document Records Electronic Archive Management

MAH: Marketing Authorisation Holder

MS: Member State

PM: Project Manager (Veterinary products only)

QRD: Quality Review of Documents

QRD form 2 - submitted by the MAH with the final translations¹ at Day 235/+25, checked and completed by secretaries and forwarded to the QRD Secretariat at Day 237/+27.

| Step | Action | Responsibility |
|------|---|----------------|
| 1 | At Day 235/+25 Check that the QRD form 2 submitted by the applicant/MAH is filled in correctly and the MSs boxes contain the correct symbols. The following symbols are allowed: ✓ - comments received and implemented; X – comments received, not all implemented; NC – confirmation received that there are no comments; n/a – no comments received from a Member State | Secretary |
| 2 | Request a revised QRD form 2 by applicant/MAH, if necessary. Repeat step 1 until the QRD form 2 is filled in correctly. | Secretary |
| 3 | Rename QRD form 2 as follows: product name followed by procedure type-variation number (e.g. for new application <name> NA; or for variations <name> II-01) Save QRD form 2 in DREAM under the relevant product/procedure folder i.e.: <i>DREAM/products/product name/procedure number/translations/final translations from MAH</i> | Secretary |
| 4 | Fill in section 2 of the QRD form 2; tick (<input checked="" type="checkbox"/>) boxes for those MSs that have sent comments or confirmed that they have no comments on the translation; leave empty (<input type="checkbox"/>) boxes for those MSs that have not commented. No other symbols should be used in this section. As this form is used for calculation of payments to the MSs, it is very important that it is filled in correctly. | Secretary |
| 5 | Check in QRD form 2 in DREAM as a new version and link it under the relevant product/procedure folder i.e.: <i>DREAM/products/product name/procedure number/ translations/final translations to EC</i> | Secretary |

¹ Applicable to the following human and veterinary procedures affecting the product information annexes: New Applications, Generic New Applications, Line Extensions, Renewals, Type II Variations, Type IB Variations, Urgent Safety Restrictions, Annual Re-assessments, Arbitrations/Referrals, Community List Entries, Annual Conditional Renewals and Article 61(3) Notifications

| Step | Action | Responsibility |
|-------------|--|-----------------------|
| 6 | <u>At Day 237/+27</u> Send via email an electronic (Word) copy of the QRD form 2 to the QRD Secretariat (email to: P-MI-PIQ). The QRD form 2 should be submitted within one week of sending the final translations to the EC. | Secretary |

END OF PROCEDURE
