



Standard operating procedure

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| Title: Handling of financial compensation for checking of product information by the member states | | |
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1. Purpose

To describe the handling by the QRD Secretariat of the financial compensation for the checking of translations of product information for human and veterinary medicinal products, performed by the Member States.

2. Scope

This SOP applies to the QRD Secretariat and Secretaries in the Human Medicines Development and Evaluation Unit, Patient Health Protection Unit and Veterinary Medicines Sector, in relation to the following procedures affecting product information:

- 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
- Article 61.3 Notifications

3. Responsibilities

It is the responsibility of each Head of Unit, Head of Sector and Section Head to ensure that this procedure is adhered to within their own unit, sector and section. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

Updated to reflect the new organisational names in the Agency, the new corporate identity and change from EDMS to DREAM. Renaming 'Product secretaries/Project Manager' to 'Secretaries' throughout the document.

- Section 2 – Addition of Type IB variations, rewording Extensions to Line Extensions and Generic Applications to Generic New Applications
- Section 5 – Linguistic Check Form (LCF) replaced by QRD Form 2; addition of WIN/EMA/0098; addition of the Payment Overview tracking table and paths to templates updated
- Section 6 –Updates to related documents and addition of the veterinary guidance document
- Section 8 - Flow chart updated to reflect changes in procedural steps
- Revision of the following steps:
 - step 1 (modified to reflect changes from LCF to QRD Form2 and inclusion of reference to WIN/EMA/0098)
 - step 2 and onwards (EDMS replaced by DREAM and QRD sec. replaced by QRD initiating agent)
 - step 4 (added 'procedure type and procedure number')
 - step 6.1 and 15 (deletion of 'line listings')
 - step 7 and 8 (modified and reworded)
 - step 9 and 11 (addition of steps to include the Payment overview tracking table)
 - steps 13, 15, 17 (addition of steps to include verification, authorisation and payment of invoice)
 - Re-numbered steps after step 8
- Section 10 (modified to include reference to the Payment overview tracking table)

5. Documents needed for this SOP

- QRD Form 2, submitted by the MAH at day +235/+25
- WIN/EMA/0098 on QRD Form 2 (former Linguistic Check Forms)
- Invoice template (Q R D - P I Q\19 Financial management\03 Financial templates and forms)
- Line listing template (Q R D - P I Q\19 Financial management\03 Financial templates and forms)
- Linguistic checking tracking table (Q R D - P I Q\10 QRD Post LinguisticTracking\01. Tracking of linguistic comments)

- Payment Overview tracking table (Q R D - P I Q\19 Financial management\01 Commitments, contracts and budget)

6. Related documents

The Linguistic Review Process of Product Information in the Centralised Procedure - Human (Doc. Ref: EMEA/5542/02/Rev.4)

(http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004182.pdf)

The Linguistic Review Process of Product Information in the Centralised Procedure - Veterinary (Doc. Ref: EMA/288844/2009 Rev 4)

(http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005250.pdf)

7. Definitions

DREAM Document Records Electronic Archive Management

MAH Marketing Authorisation Holder

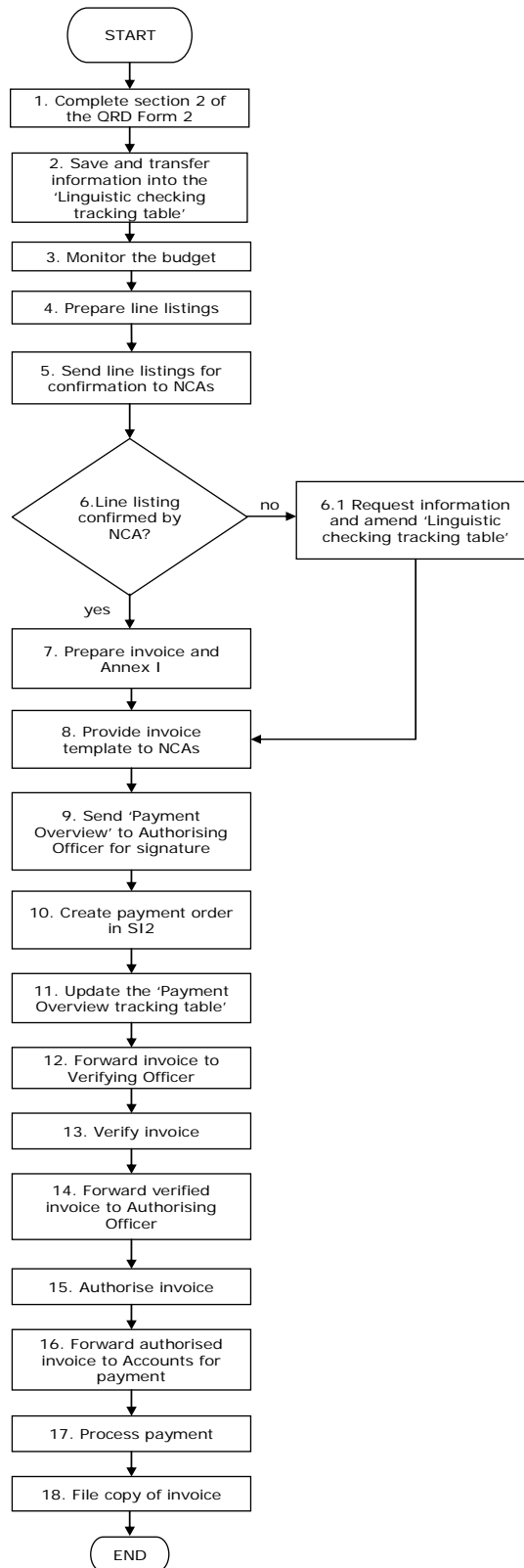
MS Member States

NCA National Competent Authorities

QRD Quality Review of Documents

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

8. Process map(s)/ flow chart(s)



9. Procedure

| Step | Action | Responsibility |
|------|---|----------------------|
| 1 | After transmitting final translations to the European Commission (Day +27), complete Section 2 of the QRD Form 2 in accordance with the WIN/EMA/0098, indicating the check performed by the NCAs between Day +5 and Day +19 [This applies to all procedures listed in section 2]. Forward the completed form to the QRD Secretariat (general e-mail address: qrd@ema.europa.eu). | Secretary |
| 2 | Save the forms in DREAM. Transfer the information from the forms into the "Linguistic checking tracking table". | QRD initiating agent |
| 3 | Carry out monitoring of the budget (budget line 3021) on a regular basis (at least once a fortnight) in order to establish levels of expected and actual expenditure. | QRD initiating agent |
| 4 | Prepare a line listing for each NCA on a bi-annual basis, in January (for the period of July-December) and in July (for the period of January-June), specifying the medicinal products, procedure type and procedure number for which a linguistic check was carried out. | QRD initiating agent |
| 5 | Send the line listing to the NCAs for confirmation. | QRD initiating agent |
| 6 | Receive the confirmation or a request for amendments from the NCA. If confirmation is received, go to Step 7 If a request for amendments is received, go to Step 6.1 | QRD initiating agent |
| 6.1 | If amendments are requested by a NCA, ask for a confirmation that the concerned check was performed (e.g. the original e-mail with comments) and amend the "Linguistic checking tracking table" accordingly, if appropriate. | QRD initiating agent |
| 7 | In case of confirmation by the NCA, prepare invoice and Annex I with the final line listing. | QRD initiating agent |
| 8 | When all line listings have been confirmed, provide an invoice template to the NCAs. | QRD initiating agent |
| 9 | Enter the payment details in the "Payment Overview tracking table" and send Payment Overview to the authorising officer for signature. | QRD initiating agent |
| 10 | After the invoice has been received by the Agency and entered in SI2 by the accountant, create a payment order in SI2 and keep a copy of the invoice. | QRD initiating agent |
| 11 | Update the "Payment Overview tracking table". | QRD initiating agent |
| 12 | Forward the original invoice together with supporting documents to the verifying officer for verification. Clarify any questions on the invoice from the verifying officer. | QRD initiating agent |
| 13 | Verify the invoice and return it to the initiating agent. | Verifying officer |
| 14 | Forward the verified invoice to the authorising officer. | QRD initiating agent |

| Step | Action | Responsibility |
|-------------|--|-----------------------|
| 15 | Authorise the invoice and return it to the initiating agent. | Authorising officer |
| 16 | After the payment has been authorised, forward the authorised invoice to the accountant for payment. | QRD initiating agent |
| 17 | Receive the authorised invoice and process the payment. | Accounts |
| 18 | File the copies of invoices. | QRD initiating agent |

10. Records

QRD Forms 2, the Linguistic checking tracking table and the Payment Overview tracking table are stored electronically in the Q R D – P I Q folders in DREAM.

Copies of invoices and supporting documents (i. e. Payment Overview signed by the authorising officer) are kept within the QRD Secretariat.