



Work instructions

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|---|-----------------------|----------------------------|
| Title: Preparation of CxMP overviews of procedures requiring Members States linguistic review | | |
| Applies to: QRD Secretariat and product secretaries in the H, P and V Units | | |
| Status: PUBLIC | | Document no.: WIN/EMA/0105 |
| Lead Author | Approver | Effective Date: 17-FEB-10 |
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| Signature: ON FILE | Signature: ON FILE | Supersedes: N/A |
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1. Changes since last revision

New WIN.

2. Records

CxMP Overview template is saved in

EDMS\Meetings\Scientific Meetings\Q R D - P I Q\02 E-mail templates - forms - table\06 Linguistic tracking templates

CHMP Table of Decisions are saved in

EDMS\Meetings\Scientific Meetings\CHMP\200x\mm-yy\TOD

CVMP Summary Records are saved in

EDMS\Meetings\Scientific Meetings\CVMP\MEETING S\SUMMARY RECORDS\CVMP Minutes 200x

Monthly CxMP overview are saved in

EMDS\Meetings\Scientific Meetings\Q R D - P I Q\10 QRD Post LinguisticTracking\01. Tracking of linguistic comments\200x\H(V) products\<month>

All e-mail templates are saved in

EDMS\Meetings\Scientific Meetings\Q R D - P I Q\02 E-mail templates - forms - table\06 Linguistic tracking templates

Translation Timetables are saved in

EDMS/products/product name/post-authorisation/post-activities/procedure number/CxMP opinion



3. Instructions

CxMP: Committee for Medicinal Products for Human Use or Committee for Medicinal Products for Veterinary Use

EDMS: Electronic Document Management System

MAH: Marketing Authorisation Holder

MSs: Member States

QRD: Quality Review of Documents

ToD: Table of Decisions

| Step/Action | Responsibility |
|-------------|----------------|
|-------------|----------------|

| | |
|----|---------------|
| 1. | QRD Secretary |
|----|---------------|

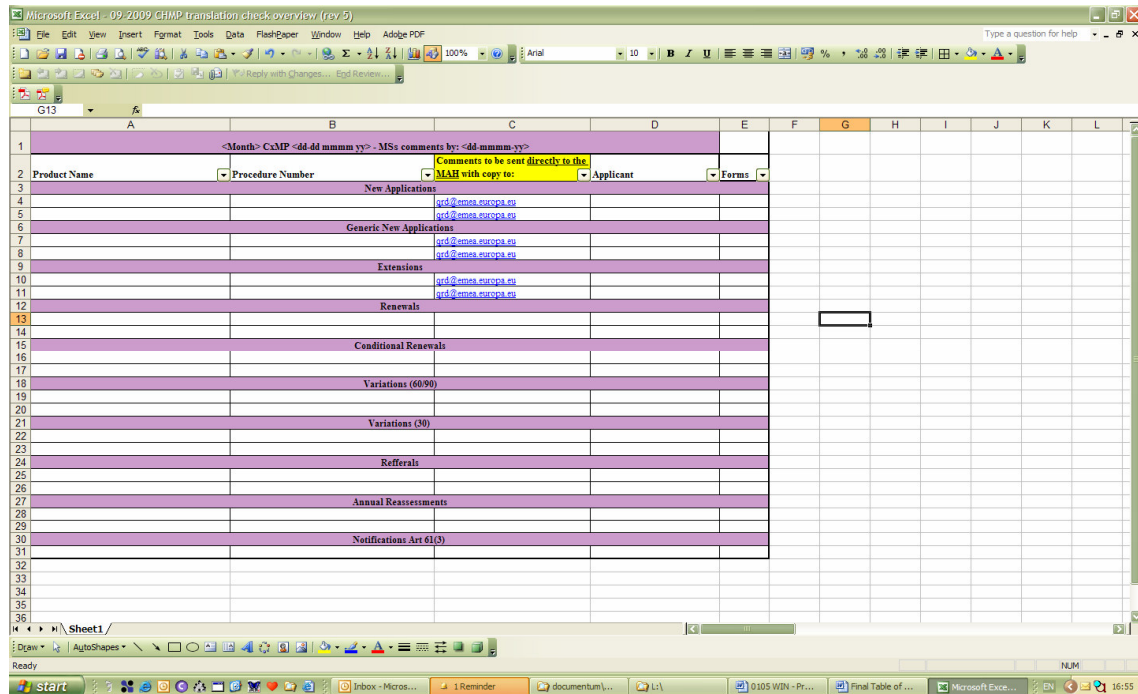
Friday after CHMP:

Print out the Draft CHMP Table of Decision saved in
EDMS\Meetings\Scientific Meetings\CHMP\200x\mm-yy\TOD

Thursday after CVMP

Print out the CVMP Summary of Records saved in
EDMS\Meetings\Scientific Meetings\CVMP\MEETING S\SUMMARY RECORDS\CVMP Minutes 200x

2. Create a new draft CxMP overview - use template named *CxMP overview* - QRD Secretary



3. In the draft CxMP overview fill in “*product name*”, “*procedure Number*” QRD Secretary and “*applicant*” columns with all the procedures that received positive opinion and will have a linguistic review.

For **CHMP**, these are listed in Draft CHMP ToD under the following sections:

| | CHMP TABLE OF DECISION |
|----------------------------|--|
| `New Applications’ | ToD sections I.3.1. & A.1.1. (full new applications) |
| `Generic New Applications’ | ToD sections I.3.1 & A.1.1. (generic new applications) |
| `Extensions’ | ToD sections I.3.1 & A.1.1. (line extensions) |
| `Variations 60/90’ | ToD sections I.3.2., I.3.3., A.1.2., A.4.1 & procedures under section A.4.2. List only those adopted with a Translations Timetable |
| `Annual Re-assessments’ | ToD sections I.3.4. & A.1.3. |
| `Renewals’ | ToD sections I.3.5. & A.1.4. |
| `Conditional Renewals’ | ToD sections I.3.5.2. |
| `Referrals’ | ToD sections I.6. |
| `Notifications Art. 61(3)’ | See step 5 |

For **CVMP**, these are listed in CVMP Minutes under the following sections:

| | CVMP MINUTES |
|----------------------------|---|
| `New Applications’ | Minutes section A.2.1. (full new applications) |
| `Generic New Applications’ | Minutes section A.2.1 (generic new applications) |
| `Extensions’ | Minutes section A.2.1. (line extensions) |
| `Variations 60/90’ | Minutes section A.2.2 - List only those adopted with a Translations Timetable |
| `Annual Re-assessments’ | Minutes section C.3 |
| `Renewals’ | Minutes section C.4 |
| `Referrals’ | Minutes section A.3. |
| `Notifications Art. 61(3)’ | See step 5 |

4. In the draft CxMP overview fill in the column QRD Secretary

“*Comments to be sent directly to the MAH with a copy to*” with either:

grd@ema.europa.eu

(for New Applications, Generic New Applications and Line Extensions)

or

[E-mail address of the responsible PTL secretary \(as stated in the Translation Timetable¹\)](#)

(for Variations, Annual Re-Assessments, Renewals, Referrals and Notifications)

5. Include any Notification Art. 61(3) received since last CxMP, if applicable.² QRD secretary

6. Save draft CxMP overview in QRD Secretary

EDMS\Meetings\Scientific Meetings\Q R D - P I Q\10 QRD Post LinguisticTracking\01. Tracking of linguistic comments\200x\H(V) products\<month>

7. Circulate the EDMS Locator of the draft CxMP overview to QRD Secretary

Product secretaries (H+V) for review

Use the e-mail template named "": *CHMP overview to product secretaries*" to send the document

8. By Monday after CxMP

Amend draft CxMP overview, where necessary and/or notify QRD Secretariat Product Secretary of any missing procedures or corrections needed

9. 30-days variations

At start of procedure, inform QRD Secretariat if a 30-days variation needs Product Secretary

Pre-opinion linguistic Review.

Send to QRD Secretariat the adopted Translations Timetable

10. Amend and finalise draft CxMP overview QRD Secretary

11. Tuesday after CxMP : QRD Secretary

Circulate CxMP overview rev. 0 to the Member States contact points³

Use the e-mail template named "CxMP overview to MS" to send the document

12. Print out a paper copy of the CxMP overview and file it in QRD Secretary

the *Workload* paper folder

13. Does the CxMP overview need amending to include additional procedures following request(s) by Product Secretaries and/or MSs?

If yes, go to step 14

If no, END OF PROCEDURE

14. Update CxMP overview highlighting any changes from previous revision QRD Secretary

Rename CxMP overview rev. 0 as CxMP overview rev.1. Save the document in EDMS

¹ Translation Timetables are saved in EDMS/products/product name/post-authorisation/post-activities/procedure number/CxMP opinion

² Product secretary to notify QRD Secretariat of any Notifications Art. 61(3) requiring a linguistic review and provide a Translation Timetable with contact details for both MAH and the Agency responsible person. The QRD Secretariat will notify the MSs and include the procedure in the next revision of the CHMP overview.

³ MS contact points mailing groups: All Human (All Vet) QRD + H-QRD (V-QRD) + H (V) POST translation contact points

15. Just after updating the CxMP overview, circulate the updated version to MSs - Use the e-mail template "*e-mail to MS-CxMP procedures requiring linguistic review*" QRD Secretary

16. Print out a paper copy of the updated CxMP overview (rev.1) and replace the one filed in the *Workload* paper folder QRD Secretary

17. Repeat steps 10-15, each time a request to update the CxMP overview is received from Product Secretaries and/or MSs. By Day 229 (deadline for MSs comments) the CxMP overview should be finalised. QRD Secretary

END OF PROCEDURE
