EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2025
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Executive Director

Multinational assessment teams

Guide for rapporteurs and coordinators

1. Background

The multinational assessment team (MNAT) concept allows the option of an assessment team to be formed from different national competent authorities (NCAs) and allows payment by EMA to the individual NCAs of the assessment team. It was initiated by the Baltic Consortium which allowed Denmark, Estonia, Finland, Iceland, Latvia, Lithuania, Norway, Poland, and Sweden to collaborate on the assessment. The concept was broadened to all Member States for Co-Rapporteurships for assessment of initial applications for human medicines.

The multinational collaboration maximises the use of available resources and expertise within the network and facilitates participation of NCAs in assessments allowing for expertise to be built up, while maintaining the high-quality scientific work of the scientific committee.

In the beginning of 2015, it was agreed by the Executive Director of EMA to formalise the concept of MNAT and to extend the scope to also include the option of Rapporteurs for human initial marketing authorisation applications (iMAA), (Co)-Rapporteurs teams for veterinary iMAA and for maximum residue limit (MRL) applications and coordinators for scientific advice procedures for both human and veterinary products.

In 2017, the use of MNATs was extended to post-authorisation and specifically to line extensions and Type II variations for extension of indication (and for veterinary medicines, addition of non-food target species) for products for which a MNAT was used for the iMAA.

Building on the experience gained in MNATs since 2015 and in view of the need to enlarge the pool of medicinal products and diversify the expertise to be accessible to MNAT for the post-authorisation phase, in 2023 the post-authorisation moved to the 2nd phase of the MNAT concept. Entering the 2nd phase allowed NCAs to access MNATs for line extensions and Type II variations for extension of indication for human medicines and variations requiring assessment with equivalent scopes[2] for

[1] Revised in October 2025 to reflect the specific steps to take for scientific advice procedures under the remit of the EMA Emergency Task Force (ETF).
[2] As detailed in the "Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations"

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veterinary medicines to the entire products portfolio, without the restriction envisaged in the 1st phase (i.e., that a MNAT was used in pre-authorisation for that medicinal product).

In October 2025, the MNAT process described in this document has been revised to reflect the specific steps to take for scientific advice procedures under the remit of the EMA Emergency Task Force (ETF).

2. Steps to be taken

2.1. Scientific advice, initial evaluation and MRL applications

- Before submitting an offer for (Co)-Rapporteurship/Coordinator role, it should be considered which types of expertise are needed for the assessment of the particular scientific advice, initial application for a marketing authorisation or MRL application, and whether assessors/co-ordinators from other NCAs are prepared to form a team (consult the rolling list of Member State expertise in relation to MNAT, if needed). MNATs for ETF scientific advice procedures can be formed also with NCAs that do not have representatives in the ETF, if their expertise is required by the appointed ETF coordinator to perform the scientific advice assessment.
- The (Co)-Rapporteur/Coordinator leading the MNAT informs the CHMP/CVMP or SAWP/ETF secretariats when submitting an offer that consists of MNAT.
- If the offer is accepted, an arrangement between the lead NCA offering the (Co)-Rapporteur/Coordinator and the participating NCAs in the MNAT should be undertaken to formally agree on distribution of work, responsibilities and percentage share of the remuneration. In cases where both CAT and CHMP are involved, the lead of the MNAT must be from the same NCA for both committees and the percentage share of the remuneration must be identical.
- For the avoidance of doubt, the lead NCA's (Co)-Rapporteur/Coordinator retains all responsibility for the quality of the relevant assessment report(s).
- If in exceptional circumstances the split in remuneration needs to be revised following receipt of the dossier, EMA will need to be informed in writing before the formal validation of the application is completed.
- EMA will inform the applicant that the (Co)-Rapporteur/Coordinator team is a MNAT.
- No later than a month before the intended submission date, the CHMP/CVMP/CAT (Co)-Rapporteur sends an email to EMA with the remuneration letter (see annex 1 to this document for template letter) setting out the distribution of remuneration amongst the members of the multinational team.
  For scientific advice, the SAWP/ETF Coordinators inform by email the Scientific Advice Office within 1 working day following formal appointment as coordinator indicating the intended split in remuneration to allow faster processing and send the remuneration letter to EMA at the latest within 5 working days following the aforementioned appointment.
  The remuneration letter is sent to the Executive Director of EMA with a copy to the following email address: financialworkflow@ema.europa.eu.
- If in exceptional circumstances after the appointment of the (Co)-Rapporteur/Coordinator it is necessary to establish a MNAT due to lack of resources, the lead NCA's (Co)-Rapporteur/Coordinator will need to request agreement from the CHMP, CVMP or from SAWP/ETF on the revised assessment team before sending the remuneration letter to EMA. As mentioned above, the remuneration letter should be sent to EMA no later than a month before the intended

submission date; or, for scientific advice, within 5 working days following the formal appointment of the Coordinators.

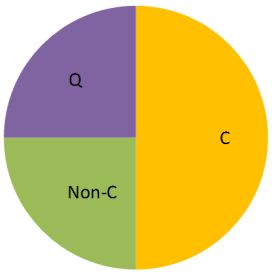
- The NCA of the lead (Co)-Rapporteur/Coordinator is responsible for the evaluation including quality of service, management of declared interests and confidentiality undertakings as per the Cooperation Agreement between EMA and the NCA.
- The (Co)-Rapporteur/Coordinator is the contact point for EMA and responsible for the communication within the MNAT.
- At the time of payment of remuneration, EMA will pay the participating NCAs directly according to the agreed share of the remuneration as set out in the remuneration letter from the NCA's lead (Co)-Rapporteur/Coordinator.

2.2. Post-authorisation – line extensions and extensions of indication applications for human medicines and variations requiring assessment with equivalent scopes for veterinary medicines

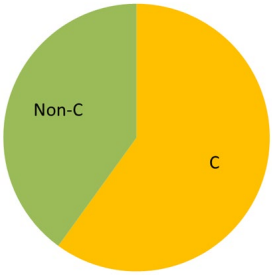
- For any product, the (Co)-Rapporteur informs EMA whether the MNAT will be applied or not for extension of indications and line extensions for human medicines and variations requiring assessment with equivalent scopes for veterinary medicines. If the assessment team will include a MNAT, the template of remuneration letter attached should be used (annex 2 to this document).
- At the time after the initial Marketing Authorisation Application Opinion, the information to apply MNAT in post-authorisation using the template Annex 2 could be sent. It should also be noted that in case EMA does not receive information as to the use of MNAT in post-authorisation prior to any submission of a post-authorisation procedure and following Opinion/Commission Decision, the payment of remuneration will be made to the (Co)-Rapporteur only. Furthermore, once the MNAT is started in post-authorisation it can be stopped before the payment is approved. The (Co)-Rapporteur must notify EMA accordingly and EMA will subsequently make the payments to the (Co)-Rapporteur only. Similarly, if the MNAT does not continue in post-authorisation immediately after opinion, it can re-start at any time during the lifespan of the medicinal product if the (Co)-Rapporteur informs EMA of the intention to apply the MNAT in post-authorisation by sending to EMA a remuneration letter.
- Any existing remuneration for the lead (Co)-Rapporteur, stemming from the pre-authorisation phase, should always be fixed in the post-authorisation phase to 10% of the total remuneration for the post-authorisation procedure. The remaining 90% of the remuneration will be distributed based on the type of data submitted as part of the procedure.
- In case the (Co)-Rapporteur wishes to apply the MNAT concept for line extensions and extensions of indication for human medicines and variations requiring assessment with equivalent scopes for veterinary medicines, guidance is provided in the template letter (annex 2) as to the remuneration and dossier distribution within the team. The relevant information is to be provided to EMA using the template letter.
- For example, for human medicines the dossier can be divided into the following parts only: quality, non-clinical, clinical pharmacology, clinical efficacy and clinical safety. For veterinary medicines the dossier can be distributed in the following parts only: quality, safety and efficacy. This means that for example the quality part of the dossier cannot be attributed to more than one NCA.

- The information is sent by email to the Executive Director of EMA with copy to the following email address: financialworkflow@ema.europa.eu. The changes will apply to the next upcoming application and cannot be applied to applications that have already been submitted.
- The NCA of the lead (Co)-Rapporteur is responsible for the evaluation including quality of service, management of declared interests and confidentiality undertakings as per the Cooperation Agreement between EMA and the NCA.
- The (Co)-Rapporteur is the contact point for EMA and responsible for the communication within the MNAT.
- At the time of payment of the remuneration, EMA will pay the participating NCAs directly according to the agreed share of the remuneration as set out in the remuneration letter from the (Co)-Rapporteur.
- The distribution of remuneration between the participating NCAs will be calculated based on the procedure type and the parts of the dossier affected by the application. For example, if an extension of indication application with only non-clinical and clinical data is submitted, only the NCAs assessing the clinical and non-clinical part of the dossier will be remunerated. The remuneration will be according to the percentages indicated. This means that if the remuneration is shared quality: non-clinical: clinical as 25%:25%:50%, then the remuneration for that extension of indication would be 1/3 of the remuneration for the non-clinical and 2/3 for the clinical (as the percentage distribution between the two is 1:2). An example is provided below:

MNAT share distribution chosen post-authorisation



Extension of indication procedure (non–C and C data) share distribution



It is important to note that in order to allow for automation of the remuneration process, the percentage of distribution of the remuneration cannot be customised to the procedure type nor changed from procedure to procedure. Instead, it is set at the product level and applicable to all eligible procedures based on the parts of the dossier being assessed and the relative contribution of each part. However, in exceptional circumstances e.g. when expertise is no longer available, there maybe changes to the NCAs participating in a MNAT with a consequent change to the agreed share of the remuneration as set out in the remuneration share letter from the (Co)-Rapporteur. In such situations, the (Co)-Rapporteur will notify EMA of such changes, and the new share distribution will subsequently be applied to all eligible procedures.

3. Contractual agreements

The Cooperation Agreement covers the relationship between EMA and the lead NCA being the (Co)-Rapporteur or Coordinator for the particular procedure.

EMA is not part of any contractual arrangement between the NCA of the lead (Co)-Rapporteur/Coordinator and the multinational assessment team and cannot give advice on a particular arrangement due to the differences in law in the various participating Member States. EMA is not responsible for any dispute arising from the contractual arrangement between the NCA of the lead (Co)-Rapporteur/Coordinator and the participating NCAs.

4. Distribution of remuneration

The percentage share of the remuneration is to be decided amongst the NCA of the lead (Co)-Rapporteur/Coordinator and participating NCAs and shall not exceed 100% corresponding to the allocated amount in accordance with Regulation (EU) 2024/568 and its Working arrangements. EMA does not have a set distribution key and will apply the distribution key that is provided in writing by the lead NCA of the (Co)-Rapporteur/Coordinator. EMA is not in a position to advise on the distribution of remuneration and will not be responsible for any dispute or difference arising out or in connection with the distribution of the remuneration. Such disputes will be resolved solely between the NCA of the lead (Co)-Rapporteur/Coordinator and the participating NCA(s).

5. Monitoring of the initiative

EMA will monitor the use of the multinational assessment teams and provide feedback to the EMA Management Board, the Heads of Agency, the scientific committees, scientific working parties and experts groups involved on a yearly basis through its Annual Report.

6. Contact point

In case of any queries relating to the multinational assessment teams please contact the EMA secretariats for the CHMP, CVMP, ETF, SAWP-H and SAWP-V as appropriate.

ANNEX 1 – TEMPLATE LETTER SETTING OUT DISTRIBUTION OF REMUNERATION FOR INITIAL APPLICATIONS/SCIENTIFIC ADVICE

Dear *[Dr, Prof, Mr, Ms XXXXX]*
Executive Director
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

[DATE]
[Reference number]

TEMPLATE LETTER

Dear *[Dr, Prof, Mr, Ms XXXXX]*,

Subject: Multinational assessment team - Payment of Rapporteur's/Co-Rapporteur's/Co-ordinator's remuneration

We refer to the appointment of our [national delegation] / [named co-opted member] ("NCA") as Rapporteur/Co-Rapporteur/Co-ordinator *[please delete as appropriate]* for the assessment concerning the medicinal product *[Please insert the name of the product]* under procedure [Please insert the procedural number and details of the procedure]. This assessment is governed by the Cooperation agreement in place with EMA and our National Competent Authority.

We wish to inform you that our assessment team will also include representatives of the following NCA(s):

[Please specify the participating National Competent Authority(ies)]

We have separately agreed with the above NCA(s) that the total remuneration set forth in the Cooperation Agreement for this assessment would be split as detailed below; taking into account that the total amount of remuneration shall remain unaltered and equal to the one set forth in the Cooperation Agreement.

Therefore, we hereby request and authorise the Agency to make direct payments to the participating NCA(s) as follows:

a) Lead NCA: % of the Rapporteur/Co-rapporteur/Co-ordinator remuneration [please delete as appropriate] supporting the quality/non-clinical/clinical part of the dossier [please delete as appropriate]

b) Participating NCA [please include the name of the NCA): % of the allocated remuneration [please include the agreed percentage of the remuneration and not a fixed amount) supporting the quality/non-clinical/clinical part of the dossier [please delete as appropriate].

We would like to confirm that the Agency will not be responsible for any dispute or difference arising out or in connection with the distribution of the remuneration as requested in this letter. Such disputes will be resolved solely between the lead NCA and the participating NCA(s).

We can also confirm that our NCA, as lead NCA, retains all responsibility for the quality of the Rapporteur/Co-rapporteur/Co-ordinator [please delete as appropriate] assessment report.

Yours sincerely
Please sign and print your name (to be signed by the Head of the lead NCA or a formally delegated person)

ANNEX 2 – TEMPLATE LETTER SETTING OUT DISTRIBUTION OF REMUNERATION AND DOSSIER DISTRIBUTION FOR POST-AUTHORISATION – LINE EXTENSIONS AND EXTENSION OF INDICATION FOR HUMAN MEDICINES AND VARIATIONS REQUIRING ASSESSMENT WITH EQUIVALENT SCOPES FOR VETERINARY MEDICINES

[Dr, Prof, Mr, Ms XXXXX]
Executive Director
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

[DATE]
[Reference number]

TEMPLATE LETTER

Dear *[Dr, Prof, Mr, Ms XXXXX]*,

Subject: Multinational assessment team post-authorisation for the product *[please insert product name]*

We refer to the appointment of our [national delegation] / [named co-opted member] ("NCA") as Rapporteur/Co-Rapporteur *[please delete as appropriate]* for the assessment of the medicinal product *[Please insert the name of the product]*.

We wish to inform you that our assessment team in the post-authorisation phase will include a multinational team with representatives of the following NCA(s):

[Please specify the participating National Competent Authority(ies)]

We have separately agreed with the above NCA(s) that the total remuneration set forth in the Cooperation Agreement for the assessment of [line extensions for human medicines] / [extension of indication for human medicines] / [variation requiring assessment for veterinary medicines[3]] would be split as detailed below; taking into account that the total amount of remuneration shall remain unaltered and equal to the one set forth in the Cooperation Agreement.

The assessments are governed by the Cooperation agreement in place with EMA and our National Competent Authority.

Therefore, we hereby request and authorise the Agency to make direct payments to the participating NCA(s) as follows:

Human medicines:

Human:		Dossier part				
	Lead NCA	Quality	Non-Clinical	Clinical - Pharmacology	Clinical - efficacy	Clinical - Safety
MS responsible						

[3] Indicate relevant scope from the "Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations"

NCA entity responsible						
Percentage remuneration	10%					

Veterinary medicines:

Veterinary:		Dossier part		
	Lead NCA	Quality	Safety	Efficacy
MS responsible				
NCA entity responsible				
Percentage remuneration	10%			

[Please fill and delete as appropriate. Please note that only one Member State/NCA entity can be responsible for a dossier part, e.g. the Quality part cannot be assigned to more than one Member State/NCA. Please also note that the percentage remuneration distribution should amount to a total of 90% since 10% of the fee of the procedure will automatically be allocated to the lead NCA. In addition, the percentage remuneration distribution cannot change within a procedure type from procedure to procedure and that the remuneration calculation will depend on the dossier parts affected by the procedure.]

We would like to confirm that the Agency will not be responsible for any dispute or difference arising out or in connection with the distribution of the remuneration as requested in this letter. Such disputes will be resolved solely between the lead NCA and the participating NCA(s).

We can also confirm that our NCA, as lead NCA, retains all responsibility for the quality of the Rapporteur/Co-rapporteur [Please delete as appropriate] assessment reports.

Yours sincerely
Please sign and print your name (to be signed by the Head of the lead NCA or a formally delegated person)