Worksharing

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What is worksharing?

• Recital 7 of the Variation Regulation:
‘In order to avoid duplication of work in the evaluation of variations to the terms of several marketing authorisations, a worksharing procedure should be established under which one authority, chosen amongst the competent authorities of the Member States and the Agency, should examine the variation on behalf of the other concerned authorities.’

• Special procedure, defined in Art. 20 of Variation Regulation (1234/2008)
What is worksharing?

• Optional procedure, not obligatory

• Open for
  ➢ type IB variations,
  ➢ type II variations, or
  ➢ group of variations (grouped application) which does not contain a line extension

for products approved through Centralised Procedure (CP), MRP or DCP

Procedure – overview

• MAH submits variation to all relevant authorities

• A ‘Reference Authority’ takes the lead in assessment (comparable to Rapporteur or RMS role)

• 60 days timetable

• Follow-up / Implementation
Reference Authority

- **EMEA** if one of the products in the group is a Centrally Authorised Product (CAP)

- **One of the MSs** if none of the products in the group is a CAP
  - MAH can provide a preference for the MS to act as Reference Authority
  - CMD(h) will choose a Reference Authority, taking into account the preference

Next slides:

Reference Authority is one of the MSs
Prior to submission

• Preferred to announce upcoming worksharing to CMD(h) 3 months in advance

• Information to be sent to CMD(h) secretariat:
  ➢ List of MAs concerned
  ➢ Description of variation
  ➢ Preference for Reference Authority
  ➢ If preferred Reference Authority has not approved all MAs, explain choice of preferred Reference Authority
  ➢ Explanation why worksharing is suitable
  ➢ Planned submission date

Suitability of Worksharing

• Same change must apply to different products

• No or limited need for assessment of a product specific impact
  ➢ If the ‘same change’ to different MAs would require submission of individual supportive data sets for each product and separate product-specific assessment → such changes would not benefit from worksharing
**Selection of Reference Authority**

- Presubmission information submitted >2 weeks in advance of CMD(h) meeting → decision will be taken at next CMD(h) meeting

- If presubmission information submitted <2 weeks in advance of CMD(h) meeting → decision will be taken at the 2nd CMD(h) meeting following submission

- MAH will be informed by CMD(h)

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**Submission**

- Variation or grouped variations must be submitted according to normal rules for application of that type of variation

- One integrated submission package covering all variations for all MAs
  - Common cover letter
  - Common application form
  - Separate supportive documentation for each medicinal product concerned

- Submission in Reference Authority and all MSs where the products are authorised
Procedure

• Validation procedure for type II variations will apply

• If preferred Reference Authority has not approved all MAs, another relevant authority may assist the Reference Authority

• Assessment report (Opinion) is always prepared (even for type IB variations)

• In general: 60 days timetable
  ➢ Can be reduced to 30 days, or
  ➢ Can be extended to 90 days for change or addition to therapeutic indication

Discussion in CMD(h)

• During procedure: no systematic discussion → Reference Authority can put it on CMD(h) agenda if felt necessary/useful

• After procedure: if no consensus → 60 days CMD referral procedure will follow
CMD(h) referral

- Also for type IB variations being part of a worksharing procedure

- In case of partial approval and no consensus: If single changes in worksharing are referred to CMD(h)
  - CMD(h) discussion deals only with single changes in question, not the whole group
  - the whole group of changes will not be approved until referral is finalised, however:
    where single changes are urgent and independent from the referred change, the Reference Authority may decide that implementation of the non-referred changes is allowed

Outcome of procedure

- Reference Authority sends it’s final opinion to all MS concerned

- In case Reference Authority is a MS:
  - Concerned MS shall approve opinion, inform the Reference Authority and amend the MA concerned within 30 days
  - If a concerned MS can not approve the final opinion, a CMD referral shall be initiated within 30 days → practical agreement to do this within 10 days, to keep 20 days for amendment of MA
  - If no CMD referral request is sent within 10 days, deemed accepted
Outcome of procedure

- In case Reference Authority is EMEA:
  - Concerned MS shall approve opinion, inform the EMEA and amend the MA concerned within 30 days
  - If a concerned MS cannot approve the final opinion, an art 31 referral shall be initiated within 30 days — practical agreement to do this within 10 days, to keep 20 days for amendment of MA
  - If no art 31 referral request is sent within 10 days, deemed accepted

Implementation by MAH

Same principles as for type II variations
- SmPC, labelling & PL changes: within 30 days unless comments received
- Other changes: after 10 days following receipt of the finalisation letter of the Reference Authority, unless an art 31 referral or a CMD referral is initiated
Worksharing procedure numbering

CC/D/nnnn/QQ/vvv

Where:
CC = two letter country code of the Reference authority
D = Domain (H or V)
nnn = placeholder: xxxx (is literally meant as ‘xxxx’)
QQ = WS (qualifier for worksharing)
vvv = sequential variation counter (four number digit)

Example: AT/H/xxxx/WS/007

Worksharing procedure numbering

AT/H/xxxx/WS/007

• The number is not product related

• Sequential variation counter (‘007’) is a new counter starting from 1 for each Reference Authority

• Number must be obtained from Reference Authority prior to submission
Worksharing vs parallel grouping

- Type IB or type II variation for duplicates with same RMS → worksharing would be possible

- RMS would become Reference Authority → parallel grouping is also an option

Worksharing not possible

- Type IA variations (unless included in a grouped application containing also type IB or type II variations)

- Extension applications

- Purely nationally approved products (for the time being)
CMD(h) expectations

- Voluntary worksharing already done by MSs, upon request by MAH
- Good experience, now formalised