



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Variations and progress in worksharing

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An agency of the European Union





Variations and progress in worksharing

The aim of this presentation is to:

- **focus on *worksharing* (what it is, types of worksharing requests, number of applications and areas for improvement)**
- **highlight *certain variations* and how the EMA works to reduce administrative burden where possible (classifications, inclusion of Croatian translations etc.)**



Progress in worksharing



What is worksharing?

Legal base is Article 20 of Commission Regulation 1234/2008:

“.....where a minor variation of type IB, a major variation of type II or a group of variations in the cases of point (b) of Article 7(2) which does not contain any extension relates to **several marketing authorisations** owned by the **same holder**, the holder of such authorisations may follow the procedure laid down in paragraphs 3 to 9 of this Article.”



Progress in worksharing

Different reference authorities depending on which types of product are included in the application -

- EMA as reference authority;
 - Two or more Centrally Authorised Products (CAPs) (CAP-only WS)
 - One or more CAPs + nationally authorised products (NAPs)/MRP/DCP (CAP-NAP WS)
- National competent authority as reference authority;
 - More than one NAP/MRP/DCP

N.B. EMA must be reference authority where a CAP involved



Progress in worksharing



- **One** integrated submission package
- For work-sharing involving CAPs the outcome is a **CVMP opinion** (and sometimes a Commission Decision) – national follow-up required for NAPs involved in CAP/NAP worksharing
- A **mixed outcome** (where a group of variations has been submitted for work-sharing) is possible i.e. some positive and some negative
- Aim is to **avoid duplication** of work



Progress in worksharing

Workshared applications can include many different products but must always comply with:

- **Same** change or **same group** of changes to each product
- **No** product-specific assessment necessary
- **Same** marketing authorisation holder

Timetable – 60 days (90 days for e.g. non-food target species)





Progress in worksharing

Types of EMA worksharing requests

- Requests include not only Type **IB** and Type **II** variations but also “**IG**” applications and large **groups** of variations
- IGs are IA variations which are “work-shared” between CAPs – the worksharing procedure does not apply to Type IA/IA_{IN} variations but under Article 7(2) of the Regulation where the same Type IA is to be submitted for a number of products to the same relevant authority a single notification may cover all such variations
- In addition, it is also possible to group Type IA or IA_{IN} variations with a Type IB or Type II variation being submitted for a worksharing procedure. In such case, the review of the Type IA or IA_{IN} variation will be performed as part of the worksharing procedure



Progress in worksharing

Types of EMA worksharing requests

- Mostly **quality / manufacturer** changes
- **IGs** are frequently **quality** and **DDPS/QPPV** related





Progress in worksharing

Number of applications:

EMA gaining in experience -

Since 1 January 2010 **22 WS** applications (includes groups)
(includes 6 CAP/NAP WS)

“IG” requests (IAs) **23 IG** applications



Progress in worksharing

Areas for improvement in the process:

- Some disappointment expressed initially by applicants that EMA was not able to accept informal workshared applications whereas CMDv could;
- Future amendment to guidance – needs to be less restrictive and allow Type IAs across procedures e.g. Detailed Description of the Pharmacovigilance System (DDPS) across all authorisations?



Progress in worksharing

Areas for improvement in the process:

- Centrally authorised products – may need an **amendment to the Commission Decision** – this increases the time to approval;
- Commission Decisions amend/update product annexes per product so **product information changes** for each product may be needed;
- Working to streamline **communication between NCAs and EMA** during worksharing procedures where EMA is reference authority



Progress in worksharing

Areas for improvement in the process:

- Worksharing is welcomed but comments received indicate that the procedure is too long for minor changes!
- Type IB workshares to be done as Type IBs? i.e. **30 days and not 60 days?**
- Aim was to reduce the administrative burden



Variations

- Procedural and Classification guidance was updated in 2013
- Some classification changes occurred – mainly due to human pharmacovigilance legislation



- The following examples – there may be others! – are particular variations which need to be highlighted



Variations

A.8 - comes about due to Falsified Medicines legislation (human only) – **not** applicable to VMPs

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Documentation

1. The variation application form should clearly outline the 'present' and 'proposed' manufacturers as listed in section 2.5 of the application form for marketing authorisations.
2. Amendment of the relevant section(s) of the dossier (presented in the EU-CTD format or NTA volume 6B format for veterinary products, as appropriate), including revised product information as appropriate.

(*) Note: where notice has been given by the authorities of the intention to perform an inspection, the deletion of the relevant site shall be notified immediately.

A.8 Changes to date of the audit to verify GMP compliance of the manufacturer of the active substance (*)	Conditions to be fulfilled	Documentation to be supplied	Procedure type
			IA

Documentation

1. Written confirmation from the manufacturer of the finish product stating verification of compliance of the manufacturer of the active substance with principles and guidelines of good manufacturing practices.

(*) Note: this variation does not apply when the information has been otherwise transmitted to the authorities (e.g. through the so-called 'QP declaration').

B. QUALITY CHANGES

Done

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Variations

C.I.3 - changes in the SPC further to PSUR: current wording means it is no longer applicable to veterinary medicines

CAPs - C.I.4 z (MRP/DCP – C.1.3 z) – both Type IB by default (reflects previous guidance)

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C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006	Conditions to be fulfilled	Documentation to be supplied	Procedure type
a) Implementation of wording agreed by the competent authority	1	1, 2	IA _{IN}
b) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH		2	II

Conditions

1. The variation implements the wording requested by the competent authority and it does not require the submission of additional information and/or further assessment.

Documentation

1. Attached to the cover letter of the variation application: reference to the agreement/assessment of the competent authority.

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Variations

Safety, Efficacy, PhV Variations: **Pharmacovigilance System**

If you have used the previous classification guidance **take care here!** The principles are the same **BUT numbering has changed:**

- ✓ Type IA: Changes to an existing PhV system (**C.I.9**)
- ✓ Type IB: New PhV system previously assessed for another product of same MAH (**C.II.7**)
- ✓ Type II: New PhV system not previously assessed for another product of same MAH (**C.II.7**)



Variations



Incorporating [Croatian](#) translations into CAP annexes

Guidance on the website but possibilities more limited for veterinary medicines – no Article 61(3):

- Include the Croatian translations in **any on-going procedure affecting the Annexes or**
- Incorporate the Croatian language versions in the **12-monthly update** procedure (i.e. without a variation) or
- Use a **C.II.6 (IA) variation procedure** in order to effect the change (which is effective immediately after the EMA notification, even if not appearing on the Commission's website)



Variations

- EMA aims to be **pragmatic** but also needs to stay within the **requirements**;
- Where possible **Type IB by default** classification is used
- Any **queries** for centrally authorised products? ----



Vet applications team

Please send email to vet.applications@ema.europa.eu and the team will be happy to help you!



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Dorota Kaczmarczyk



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Thank you for your attention!