EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Procedural updates and organisation

Update on variations and progress in work-sharing

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An agency of the European Union

Update on variations and progress in work-sharing

- Reminder on **Type IA variations**

- Update on **Work-sharing**

Update on variations and progress in work-sharing

Reminder on Type IA variations (updated approach):

- Type IA variations: fee becomes due on the date of receipt of the type-IA or -IA_{IN}-variation notification - fee payable within 45 calendar days
- After approximately 15 days, an invoice will be sent to the applicants billing address held on the Agency's file

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- No stand-alone notifications of purchase order numbers not associated with a dossier please (!) but rather provide the information in the formatted table template
- The fee for type-IA variations or grouped type-IA variations is charged at the start of the procedure, **irrespective of its outcome (positive, negative, or partial or full withdrawal)**.
- *N.B. Type-IA variations grouped with other type of variations or extensions or which are part of a **work-sharing** procedure will continue to be charged on conclusion of the validation of the application.*

Update on variations and progress in work-sharing

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 the reference authority where a CAP involved

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Work-shared 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

In general a 60-day evaluation timetable is applied (may be reduced – safety issues - or extended - e.g. changes or additions to the therapeutic indication)

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- **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 work sharing
- 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

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Application numbers:

- 2012: **8 WS** & **2 IG** (IG = IA CAP-only work-shares)
- 2013: **8 WS** & **11 IG**
- 2014: **14 WS** & **11 IG**

Totals **30 WS involving some 45 products**

24 IG involving some 66 products

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Thank you for your attention!