

Information on fees for variation applications

In relation to the new Variation Regulation (EC 1234/2008) which came into force 1 January 2010 (with implementation for national variations by 1 October 2010), the authority's application of the Fee Ordinance for grouping and worksharing is clarified below.

The Medical Products Agency will also henceforth consistently charge fees per product (trade name) for all variations which are not included in the annual fee.

Interpretation of the Fee Ordinance for Grouping according to Art 7:

- a) Grouping of variations of type IA and/or IB for one product
 - *Fee:* Included in the annual fee
- b) Grouping of the same type IA variation(s) for more than one product
 - Fee:* Included in the annual fee
- c) Grouping of two or more variations for one product, of which at least one variation is type II
 - *Fee:* One fee per variation type II
- d) Grouping of two or more variations of type IA, type IB and/or type II for one product, where also one or more extensions are included
 - *Fee:* One fee per variation type II and one fee per extension

Please observe that grouping for one or several variations concerning more than one product only applies to type IA variations.

Interpretation of the Fee Ordinance for Worksharing according to Art 20:

- a) Worksharing for type IB variations
 - *Fee:* Included in the annual fee
- b) Worksharing for a number (x) of products where one or more type II variations are included with SE as the Reference Authority (RMS) for the worksharing procedure:
 - *Fee:* x number of fees for type II variation with SE as RMS

Example: SE/H/xxxx/WS/0011 including:

- SE/H/0102/001
- SE/H/0113/001-002
- FR/H/0020/001

concludes that three fees for type II variation with SE as RMS will be charged

- a) Worksharing for a number (x) of products where one or more type II variations are included with SE as CMS in the worksharing procedure:

- *Fee:* x number of fees for type II variation with SE as CMS

Example: DE/H/xxxx/WS/0003 including:

- DE/H/0233/001
- DE/H/0234/001-002
- SE/H/0113/002

concludes that three fees for type II variation with SE as CMS will be invoiced

- b) Worksharing where one or more type II variations are included and a number (x) of products are approved via MRP or DCP (with SE as RMS or CMS) and the remaining products are approved via the centralised procedure. EMA will be the "Reference Authority" and the procedure will be managed as a centralised procedure during the assessment phase, for products approved via MRP or DCP a national phase will follow.

- *Fee:* x number of fees for type II variation with SE as CMS (in addition to the fee that will be invoiced by the EMA.)

Example: EMA/H/xxxx/WS/0021 including:

- EU/H/0375/001-003
- EU/H/0222/001
- UK/H/0222/001-002
- SE/H/0373/001-002
- FR/H/0020/001

concludes that three fees for type II variation with SE as CMS will be invoiced by the MPA regardless if SE acts as Rapporteur or not for the worksharing procedure. (A fee will also be invoiced by the EMA from which the MPA will get a share as Rapporteur but not as MS.)

Abbreviations

MPA	Medical Products Agency
EMA	European Medicines Agency
SE	Sweden
MS	Member State
RMS	Reference Member State
CMS	Concerned Member State
DCP	Decentralised Procedure
MRP	Mutual Recognition Procedure