Impact assessment study for the revision of the EMA fee system: consultation FAQs

1. Q: Several individuals within my organization have received an invitation for the survey. Should they each reply to the questionnaire or is one entry sufficient?

A: One submission per organization is preferred. If there is a difference in opinion between different parts of an organisation, we will accept multiple submissions and take these different views into account. Please note that the responses should reflect the views of the organization (or parts of the organization) rather than those of any individual within it.

1. It has come to the attention of the study team that there were errors in the fee grids, which support the completion of the survey. These have been checked and corrected, with the changes summarized below, including summary tables showing the specific changes made.

Please note that in the new fee grids, the corrected cells are now highlighted in yellow.

The following issues were identified, and corresponding changes have been made to the fee grids:

* 1. **Option 1**: **fees for *human procedures only* were misaligned**. One of the PhV referral levels was omitted, which affected the fees from PASS onwards.

However, **under option 1 human fees and remuneration are unchanged from the do-minimum** apart from the Darwin contribution to the annual fees, therefore **this should not affect your analysis of the option**.

* 1. **Option 2 and Option 3 ‘light’**: **Type II variation fees and remuneration for *human medicines procedures only*** have been increased following a change to the classification of Type II variations in Option 2 relative to the existing system.
  2. **Option 3 light**: **CAP annual fees for *veterinary and human medicines*** were miscalculated. This has been corrected.
  3. **Option 3**: **CAP annual fees for *veterinary medicines only*** were miscalculated. This has been corrected.
  4. **Option 3**: **CAP annual fees and associated annual NCA remuneration for *human medicines only*** were adjusted, to reflect the correction specified in point 2 above. This is also because the Type II variations do not have separate fees and remuneration in this option but are covered by the annual fees and NCA payments.

These changes are specific to a small number of fees and in most cases should not impact your responses to the survey if you have already submitted it. However, having reviewed the changes, if you would like to make changes to a survey response already submitted we will assist you in this matter. Please contact us

at [emafeesystem\_study@icf.com](mailto:emafeesystem_study@icf.com) if you have any questions or wish to make any changes to your organisation’s survey response.



