

COVER LETTER

{Letter head Transferor} *(to be signed by the Transferor's contact person)*

{Date}

{EMA/V/C/xxx}, {Product Name (active substance(s))} (medicinal product(s) concerned)

Re: Application for Transfer of Marketing Authorisation from {name Transferor} (the Transferor) to {name Transferee} (the Transferee)

Dear Sir or Madam

*(Free text)*

The following documents are enclosed:

- Attachment 1 (signed by the Transferor and the Transferee)
- Attachment 2 (signed by the Transferor and the Transferee)
- Attachment 3 (signed by the Transferee, and also by the QPPV for section b) only)
- Proof of establishment of the Transferee within EEA issued in accordance with national provisions and not older than 6 months
- Confirmation from the Agency of the acceptability of the new name following the name check procedure, if applicable.
- Product information Annex I, II and III bearing the name of the Transferee in all EU languages, Icelandic and Norwegian
- English and multi-lingual ('worst-case') colour mock-ups of the outer and primary packaging bearing the details of the Transferee *(there is no obligation to provide mock-ups but it is recommended in case the overall artwork design is affected by the changes)*

Yours Sincerely/Regards/Best Wishes,

{Title, name, position}

For and on behalf of {name Transferor}  
(The 'Transferor')