*[to be signed by the Transferor’s current contact person/company authorized for communication between MAH and the competent authorities (2.4.****3*** *of the application form)]*

{Date}

{EMEA/H/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)*

***[Provide the relevant information, as applicable:***

***1)*** *For orphan products: The cover letter should contain confirmation that the transfer of the orphan medicinal product designation (see also https://www.ema.europa.eu/en/transfer-orphan-designation) has been submitted in accordance with Article 5(11) of Regulation (EC) No 141/2000 in order to maintain the orphan status.*

*Please include the case number of the transfer of the OMP designation and the submission date in the* [*IRIS system*](https://iris.ema.europa.eu/)*.*

***2)*** *If the product’s name is <INN>+<Company name: The cover letter should contain confirmation that the appropriate variation (see also https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/changing-invented-name-centrally-authorised-medicine-questions-answers) to change the product name has been submitted/approved or a justification should be provided.*

***3)*** *SME status: If applicable, the SME status and SME number of both the transferor and transferee should be stated in the cover letter.*

***4)*** *For a Transferee established in Ireland: The cover letter should contain confirmation that if the transferee wants English to be the authentic language for their product information and the decisions addressed to them by the European Commission, a language waiver request has been applied for. Such waiver request should be sent to* [*IrishWaiver@ema.europa.eu*](mailto:IrishWaiver@ema.europa.eu) *using the relevant* [*form*](https://www.ema.europa.eu/en/documents/template-form/irish-language-waiver-request-template_en.docx)*.* *Background information is available at the* [*EMA website*](https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information-requirements#irish-language-(new)-section)*.]*

*Please include confirmation of this application submission date.*

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)
* Proof of establishment of the Transferee within EEA issued in accordance with national provisions and not older than 6 months
* Updated 1.8.1 Module (Summary of PSMF)
* Product information Annex I, II and III bearing the name of the Transferee in all EU languages, Icelandic and Norwegian; Word annotated and (Clean PDF) version**[[1]](#footnote-1)**
* Completed [Checklist for the submission of product information annexes and Annex A (if applicable)](https://www.ema.europa.eu/en/documents/template-form/checklist-submission-type-ia-type-ib-without-linguistic-review-product-information-annexes-annex-if-applicable-human_en.docx)
* English and multi-lingual (‘worst-case’) colour mock-ups of the outer and immediate packaging bearing the details of the Transferee

Yours sincerely,

{Title, name, position}

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

1. Files comply with the [user guide on how to generate PDF versions of the product information](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/user-guide-how-generate-pdf-versions-product-information-human_en.pdf) (i.e. naming convention was followed, bookmarks and document properties have been applied) [↑](#footnote-ref-1)