{Letter head Transferee} *(to be signed by the Transferee)*

{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)

**Attachment 3**

Information showing the capacity of Transferee to perform all the responsibilities required of a MAH under the Union Pharmaceutical legislation.

**a) Identification of the person/company authorised for communication between the Transferee and the agency after authorisation on the Transfer of the marketing authorisation.**

This is to confirm that the contact person whose details are provided below is authorised for communication between the marketing authorisation holder (MAH) and the European Medicines Agency after the completion of the Transfer of marketing authorisation for the medicinal product(s) concerned**[[1]](#footnote-2)**.

|  |
| --- |
| Person/Company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation of the Transfer.  {Title}: {First name}: {Surname}:  {Company name (*from OMS***[[2]](#footnote-3)**)}:  {Address}:  {Country}:  {Telephone}:  {E-Mail}: |

**b) Summary of the pharmacovigilance system master file.**

The transferee hereby confirms that a Summary of the Pharmacovigilance system with respect to the transferred medicinal product(s) and containing the information listed in Article 8(3)(ia) of Directive 2001/83/EC is provided with this transfer application.

**c) Identification of the scientific service in charge of information about the medicinal product as referred to in Article 98 of Directive 2001/83/EC.**

The Transferee hereby confirms that whose details are provided below is the authorised person responsible for scientific services (within the meaning of Article 98 of Directive 2001/83/EC) for the medicinal product(s) concerned.

|  |
| --- |
| Scientific service of the MAH in the EEA as referred to in Article 98 of Directive 2001/83/EC.  {Title}: {First name}: {Surname}:  {Company name (*from OMS*)}:  {Address}:  {Country}:  {Telephone}:  {E-Mail}: |

**d) Identification of the contact person in the EEA for product defects and recalls within the meaning of Article 79 of Directive 2001/83/EC.**

The Transferee hereby confirms that the contact person whose details are provided below is the authorised person responsible for quality defects and batch recall for the medicinal product(s) concerned.

|  |
| --- |
| **Contact person in the EEA for product defects and recalls.**  {Title}: {First name}: {Surname}:  {Company name (*from OMS*)}:  {Address}:  {Country}:  {24H telephone}:  {E-Mail}: |

Yours sincerely,

|  |  |
| --- | --- |
| {Title, name, surname, position} |  |
| For and on behalf of {name Transferee} (The Transferee) |  |

1. At the time of the submission, please make sure that the contact is registered at [Home · EMA Account Management (europa.eu)](https://register.ema.europa.eu/identityiq/home.html) [↑](#footnote-ref-2)
2. All organisations (name and address) for Transferor and Transferee as well as contact persons should be reflected in line with SPOR OMS. The associated LOC and ORG codes can be included. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information [OMS Web UI (europa.eu)](https://spor.ema.europa.eu/omswi/#/) [↑](#footnote-ref-3)