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

{Date}

{EMEA/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)

**Attachment 1**

Information on **a)** the medicinal product(s) concerned; **b)** on the transferor and transferee;
**c)** declarations that all information regarding the product has been made available to the transferee with a statement of undertaking from the transferee, and **d)** updated product information as per the requirements of Commission Regulation (EC) No 2141/96 .

**a) Medicinal product(s) concerned**

The marketing authorisation to be amended by this Transfer procedure relates to the following medicinal product:

|  |  |
| --- | --- |
| Name of the Medicinal Product: |  |
| Active Substance(s): |  |
| Marketing Authorisation Number(s): | {EU/…} |
| Date of Marketing Authorisation\*: |  |

\* *Mentioned in the section “Authorisation details” of the product-specific webpage on the EMA website*

**b) Identification of the Transferor and the Transferee**

|  |  |
| --- | --- |
| Name and address of the Transferor:{OrgID} *(from OMS)*{LocID} *(from OMS)* | Name and address of the Transferee[[1]](#footnote-2):{OrgID} *(from OMS)*{LocID} *(from OMS)* |
| {Title, name and surname of the Contact person at transferor address[[2]](#footnote-3)}{Telephone}{E-mail} | {Title, name and surname of the Contact person at transferee address}{Telephone}{E-mail} |

🞎 A proof of establishment of the Transferee within the European Economic Area issued in accordance with national provisions and dated within the last six months is provided

**c) Declaration that the complete and up-to-date file concerning the medicinal product or a copy of this file including <information regarding any outstanding post-authorisation measures> has been made available or has been transferred to the Transferee**

The current marketing authorisation holder (the Transferor), hereby certifies that the complete and up-to-date file(s) concerning the above-mentioned product(s) or a copy of the file(s), including <information regarding any outstanding post-authorisation measures>, has/have been made available to or has/have been transferred to the Transferee.

The person to whom the transfer is to be granted (the Transferee), hereby certifies that the complete and up-to-date file(s) concerning the above-mentioned product(s) or a copy of the file(s), including <information regarding any outstanding post-authorisation measures>, has/have been made available by or has/have been received from the Transferor.

🞎 There are no outstanding post-authorisation measures

🞎 The Transferee agrees to undertake the following remaining post-authorisation measures (PAMs) requested by the <CVMP> and commits to submit the data listed below within the specified timeframes as requested by <CVMP>.

List of outstanding post-authorisation measures requested by the <CVMP> with
their due dates:

|  |  |  |
| --- | --- | --- |
| **Area** | **Description** | **Due Date** |
|  |  |  |

**d) Updated Product information as per the requirements of Commission Regulation (EC) No 2141/96**

Transferee and Transferor hereby certify that no other changes have been made to the content of the Product Information Annexes I, II and III other than those pertaining to the details of the MAH <and the list of local representatives>.

Yours sincerely,

|  |  |
| --- | --- |
| {Title, name, surname, position}[[3]](#footnote-4) | {Title, name, surname, position}**[[4]](#footnote-5)** |
| For and on behalf of {name Transferor}(The Transferor) | For and on behalf of {name Transferee}(The Transferee) |

1. The address given must correspond to the address in SPC section 6, and be in accordance with OMS. [↑](#footnote-ref-2)
2. Contact person at the MAH address referred to in section 2.4.1 of the application form for initial marketing authorisation application; the telephone number must be from the same country. This information should be kept up to date and any changes (including during the post-authorisation phase) notified to the Agency promptly. [↑](#footnote-ref-3)
3. The signature of the Transferor applies to all sections of this letter except for the Statement of undertaking, which is to be signed only by the Transferee. [↑](#footnote-ref-4)
4. The signature of the Transferee applies to all sections of this letter including (but not limited to) the Statement of undertaking. [↑](#footnote-ref-5)