<MAH name
MAH address 1>

dd/mm/yyyy

To: Medicines Authority

Re: Product Name, [EU number, if applicable], [MA number]

The applicant/MAH declares that the applicant has:

- At his disposal a qualified person responsible for pharmacovigilance
- The necessary means to fulfill the tasks and responsibilities in Title IX of Directive 2001/83/EC.

<In line with legal requirements, the marketing authorisation holder has, as a result of the intention to transfer the product, updated the following details through the Article 57 database:

- The Member state in which the qualified person resides and carries out his/her tasks
- The contact details of the qualified person
- Reference to the location where the pharmacovigilance system master file for the medicinal product mentioned above is kept>.

<OR>

<The proposed MAH will make use of the same QPPV as the current MAH; as a result the article 57 details have not changed>

AND

The proposed MAH <will make use of the same PSMF as the current MAH>/<will make use of another PSMF different from that of the current MAH>

<Where applicable:>
I, MAH/Applicant, also declare that a variation to update the PSMF summary (Annex 1.8.1) will be submitted < to the RMS and CMSs> <to the Medicines Authority>

_____

Name/surname, signature and designation of Applicant/Proposed Marketing authorization holder or person authorized on his behalf (please attach letter of authorization)

_____

Name/surname and signature of QPPV