Name and address of the MAH

(or Power of Delegation)

|  |
| --- |
| FormVRA– VARIATION REQUIRING ASSESSMENT |

|  |  |
| --- | --- |
|  | Name of the medicinal product: |
|  | Pharmaceutical form and dosage: |
|  | UPD Permanent identifier: |
|  | UPD product identifier: |
|  | Marketing authorisation LU Number : |
|  | NAP or MRP or DCP or SRPProcedure number : RMS : |
|  | Code for the variation : |
|  | Does this variation lead to an update of product information in UPD by the CMS?If yes, please explain what information must be updated in UPD. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Number of variations requested |  |  |  | Total amount to pay  |
|  |  | X | 150 € |  |  |

The following supporting documents must be attached to the form::

Name and contact details of contact person

• Email:

**Description of the proposed amendment**:

The following supporting documents shall be attached to the notification:

* a copy of the delegation of authority if you are acting on behalf of the MA holder
* approval of the VRA by the RMS for DCP/MRP
* approval of the VRA by the country of origin (FR-BE -DE) for national procedures (NAP)
* if applicable, a copy of the new texts (SPC, PI PL)
* the proof of payment of the VRA(s) :

IBAN : LU36 0019 5955 4436 2000

SWIFT/BIC: BCEELULL SPUERKEESS

Banque et Caisse d’Epargne de l’Etat, Luxembourg

Name of the applicant

(Person having power, according to the statutes of society, to engage society)

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_