##### (< FROM CEP HOLDER ON HEADED PAPER>)

#### TEMPLATE LETTER OF ACCESS

[Date]

CEP number:

Name of the Substance:

Subtitle (if applicable):

CEP holder: [name and address]

The aforementioned CEP Holder hereby authorises [Name of Marketing Authorisation Holder/Applicant] to refer to the above mentioned CEP in support of the following Marketing Authorisation Application(s) or Marketing Authorisation Variation(s):

[Name of product (if known)]

[Name of Applicant or Marketing Authorisation holder]

The aforementioned CEP holder commits to ensure batch-to-batch consistency, to share sufficient information to enable [Name of Marketing Authorisation Holder/Applicant] to take full responsibility for an evaluation of the suitability of this substance for use in the manufacture of the aforementioned medicinal product and to inform them of any relevant change in the CEP dossier.

Signature for the CEP holder

[Name and function]

[Signature]