**Template for the notification of step 1 risk evaluation outcome: risk identified**

*(< FROM MAH ON HEADED PAPER >)*

<Date>

*Name of company,*

*Address*

**RE: Risk evaluation outcome: confirmation of risk of nitrosamine presence identified**

Dear <Name>,

I herewith confirm that, having performed the requested risk evaluation applying principles outlined in

in CHMP’s Article 5 (3) opinion EMEA-H-A5(3)-1490, the product <Name>, <Active Pharmaceutical Ingredient>, <Marketing Authorisation Number>, <EU Procedure Number (for MRP/DCP products only)>, was identified to be at risk of presence of nitrosamines.

Confirmatory testing is planned to start on <Insert timeline for confirmatory testing> and is expected to be completed by<Insert timeline for completing confirmatory testing> . An update will be provided by <Insert timeline for update>.

I herewith attach the completed excel spreadsheet.

I herewith confirm that the review performed was adequately documented and risk evaluation documentation can be made available upon request.

Yours sincerely,

<Signature of authorised contact person>

<MAH>