**Template for the notification of step 2 confirmatory testing outcome: confirmation of nitrosamine detected**

*(< FROM MAH ON HEADED PAPER >)*

<Date>

*Name of company,*

*Address*

**RE: Confirmatory testing outcome: confirmation of nitrosamine detected**

Dear <Name>,

I herewith confirm that, having performed the requested confirmatory testing for the product <Name>, <Active Pharmaceutical Ingredient>, <Marketing Authorisation Number>, <EU Procedure Number (for MRP/DCP products only)>, the following nitrosamine(s) was identified: <List the nitrosamine(s) identified>. Indicate if the nitrosamine (s) detected are newly identified nitrosamines which were not included in CHMP article 5 (3) opinion or EMA/CMDh Q&A on nitrosamines. In case of new nitrosamine identified, complete “Step 2 Nitrosamine detected above AI or new nitrosamine detected response template” irrespective of the amount detected. <This is a new nitrosamine>.

The acceptable intake limit (AI) calculated is (report the calculated limit in ng and ppm):

<For newly identified nitrosamine which was not included in the CHMP article 5(3) opinion or EMA/CMDh Q&A on nitrosamines please tick as follows either:

General class specific TTC (18ng/day) in line with CHMP article 5(3) Q&A is being applied

Substance specific AI limit (including SAR considerations) is being applied>

I declare that the content of the nitrosamine (s) identified is (select one option):

exceeding the AI or exceeding the lifetime excess cancer risk of 1:100,000. Therefore, I enclose testing results in ppm and interim investigation report including, risk mitigating plan and benefit/risk assessment. Complete “Step 2 Nitrosamine detected above AI or new nitrosamine detected response template”.

not exceeding the AI or the lifetime excess cancer risk of 1:100,000 but its content is above 10% the AI. I declare that I intend to submit the following variation scope <indicate scope> by <Indicate timeline>.\*

is consistently below 10% of the AI or the risk level of 1:100,000 and therefore no variation will be filed.

\* Please note that a tick-box has been implemented in the eSubmission Gateway XML delivery file for variations therefore applicants are required to indicate whether a variation is related to the call for review before it can be submitted.

Yours sincerely,

<Signature of authorised contact person>

<MAH>