**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 are not included in CHMP article 5 (3) opinion or EMA/CMDh Q&A on nitrosamines Appendix 1. In case of new nitrosamine identified, complete “Step 2 Nitrosamine detected above AI or new nitrosamine detected response template” irrespective of the amount detected. Complete the details for appointment of lead MS below+.<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 Appendix 1 please tick as follows either1:

The proposed AI is determined based on the Carcinogenic Potency Categorization Approach (CPCA)

Other data is submitted in support of the proposed AI (results of an Ames test, an *in-vivo* mutagenicity study or data supporting a read across approach) >

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>*2, 3.

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

I confirm that the testing activities performed were adequately documented and related documentation can be made available upon request.

***+****Where Scenario A (detection > AI) applies, or a new nitrosamine has been identified for a purely national marketing authorisation, please also indicate here if the product is authorised in other member states and the same data package applies:*

*Please then provide the list of affected MS and authorisation numbers. A preferred lead Member state may also be proposed:*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_<list affected MS and proposed preferred lead MS>*

*1 This paragraph is only applicable in case a final AI has not yet been published in the EMA/CMDh Q/A on nitrosamines.* *Once an AI is published there, it is mandatory to be used and these tick boxes cannot be used anymore.*

*2 When the variation(s) under Step 3 have been submitted, please send a notification to the email addresses (‘the nitrosamines mailboxes’), to the concerned national competent authorities in case of purely national MA’s and to the RMS in case of MRP/DCP products (copying the CMS’s) including “Submission of variation- nitrosamines – Step 3” in the heading. The notification should outline the details of the authorised product(s) and date of submission of the relevant variation. The Member State’s reference number for the variation case should be provided or in the case of the MRP/DCP products, the EU procedure number should be stated. Work sharing according the CMDh BPG Chapter 7 Worksharing, is highly recommended for these variations.*

*3 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>