Risk of nitrosamine presence identified
Contact person (First name and surname) *
E-mail *
Local representative
Marketing Authorisation Holder name *
Marketing Authorisation Holder address and country *
Product name * Footnote: Strength and dosage form is not a part of the product name.
Active pharmaceutical ingredient (API)* Footnote: If product contains more than one active pharmaceutical ingredient, please separate the APIs with a comma
Marketing Authorisation Number * Footnote: please try to use the correct format, e.g 17-12345, when filling the MA number. For the MA number in correct format, please confer with the most recent issued approval letter issued by NoMA for the MA's in question. If more than one MA number, please separate the numbers with ,
Procedure type ☐ MRP/DCP ☐ NP *If the MRP/DCP box Is ticked you will be asked to fill in the procedure number*
Procedure Number *
Is the risk associated with; ☐ Finished product ☐ API
How many API manufacturers are registered for the product? 1-2-3-4-5 *You will be asked to fill in the name and address for all API manufacturers.*
API manufacturer name *
API manufacturer address and country *
Does the medicinal product contain more than one API? ☐ Yes

☐ No *If yes you will be asked to fill in the name of the manufacturers for the different APIs*
Please list the names of the manufacturer for the different APIs
How many finished product manufacturers are registered for the product? 1-2-3-4-5 *You will be asked to fill in the name and address for all finished product manufacturers.*
Finished product manufacturer name *
Finished product manufacturer address and country *
Date for approved risk assessment (DD.MM.YYYY) *
Start of testing (DD.MM.YYYY) *
Scheduled date for completion of testing (DD.MM.YYYY) *
Scheduled date for submission of information requested in Step 2 (DD.MM.YYYY) *
Upload signed version of this form * (lenke til skjema)
Upload Excel spreadsheet * (lenke til skjema)