# Et bilde som inneholder skjermbilde, sort  Automatisk generert beskrivelse

# Application – batch specific variation

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| **Information about the medicinal product** |
| Name, strength, pharmaceutical form:       |
| Active substance:       |
| Pack size:       | Number of packages:       |
| MA number:       | Batch number:       |

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| **Information about the deviation** |
| The deviation is related to:[ ]  quality[ ]  delayed implementation of product information |
| Background for the deviation:       |
| If relevant, when should variation in product information have been implemented? Please state date:      Expected implementation date:       |

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| **Information about the action to be taken** |
| What actions have been made and what does the applicant suggest to solve the delay:       |
| Will a rejection cause a shortage situation in Norway? [ ]  Yes [ ]  NoAre there similar medicinal products on the Norwegian market? [ ]  Yes [ ]  No |

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| **Attachments** |
| **Batch specific variation regarding delayed implementation of product information**[ ]  Last approved package leaflet with tracked changes and/or mock-ups**Batch specific variation regarding quality**[ ]  Risk assessment based on relevant competent evaluation for the sake of supporting the application. |

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| **Information about the marketing authorisation holder or local representative**  |
| Company name:       |
| Contact person:       |
| E-mail:       |

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| **Invoice**  |
| Company name and address:       |
| Contact person:       |
| E-mail:       |

Please submit this application form together with last approved package leaflet and/or mock-ups and/or risk evaluation to post@noma.no