# 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  No  Are 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](mailto:post@noma.no)