Notification of a Change(s) to the Key Information of a Product Approved by a Stringent Regulatory Authority (SRA)

**Please note that a separate notification should be submitted for each finished pharmaceutical product (FPP).**

Please complete each section of this application form electronically as a Word document and as a scanned signed PDF file. Submit in electronic format; no hard copies are required.

# Product and administrative details

## Associated FPP name /PQ ref. number:

*e.g. Zidovudine 100mg Capsules – HA108*

## Administrative details

Please note that the contact listed in the table below will be the primary contact for communication for this specific application.

|  |  |
| --- | --- |
| Applicant |  |
|  |  |
| **Primary contact person responsible for this application** | Title:  First name:  Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** | |
| **Unit** |  |
| **Building/PO Box Number** |  |
| **Road/Street** |  |
| **Plant/Zone** |  |
| **Village/Suburb** |  |
| **Town/City** |  |
| **District/Mandal** |  |
| **Province/State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

If there are other contacts who should be routinely copied into correspondence for this application they should also be listed below.

|  |  |
| --- | --- |
| Additional contact person | Title:  First name:  Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** | |
| **Unit** |  |
| **Building/PO Box Number** |  |
| **Road/Street** |  |
| **Plant/Zone** |  |
| **Village/Suburb** |  |
| **Town/City** |  |
| **District/Mandal** |  |
| **Province/State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

|  |  |
| --- | --- |
| Additional contact person | Title:  First name:  Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** | |
| **Unit** |  |
| **Building/PO Box Number** |  |
| **Road/Street** |  |
| **Plant/Zone** |  |
| **Village/Suburb** |  |
| **Town/City** |  |
| **District and Mandal** |  |
| **Province/State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

# Summary of SRA-approved changes(s) with this submission

|  |  |  |
| --- | --- | --- |
| Reference SRA | SRA-approved change (short description) | Date of SRA approval or implementation |
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|  |  |  |
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| --- | --- | --- |
| **Documentation affected by the reference SRA-approved change(s)** | | |
| **The change(s) affect(s) 1**  **(Tick applicable box(es) in last column with “X”)** | The QIS-SRA 2 |  |
| The product information 3  Weblink (if available): |  |
| The FPP specifications (release and/or shelf life) 4 |  |
| The analytical test procedures 5 |  |

1. Only SRA-approved changes affecting the Quality Information Summary (QIS)-SRA, the product information, the FPP specifications and test procedures should be reported. The QIS-SRA is available on the WHO prequalification website.
2. Submit the revised QIS-SRA, highlighting the changes. (For FPPs that have been prequalified according to the SRA route prior to implementation of the QIS-SRA, the QIS-SRA template should be completed in full whenever variations that affect the QIS-SRA have been approved by the reference SRA, highlighting the revised sections.)
3. Submit the Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and/or label, showing changes in track changed mode, as well as a certified clean English language version of the latest product information (in Word), and the web link to the product information on the SRA website, if applicable. When the product information is publicly available in English on the SRA's website, submission of the update of the product information (e.g. SmPC/PIL) can be waived.
4. Revise QIS-SRA and submit PDF copies of signed/dated specifications.
5. Submit PDF copies of test procedures, indicating changes in tracked change mode.

**3. Declaration**

I declare that (*Please check the appropriate declarations*):

SRA acceptance letter(s) for the change(s) are attached to this form.

As a result of the changes described that affect the QIS information, the QIS-SRA is included, with revised sections highlighted.

As a result of the changes described copies of the revised SmPC, PIL and/or container labels (immediate and outer) are included, with changes indicated in tracked change mode.

As a result of the changes described copies of the revised FPP specifications (release and shelf life) are included.

As a result of the changes described copies of the revised FPP test procedures are included, with changes indicated in tracked change mode.

The information submitted is true and correct.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_